



Clinical Development

lutetium (¹⁷⁷Lu) vipivotide tetraxetan

AAA617 ([¹⁷⁷Lu]Lu-PSMA-617)

SCS Appendix 1 (Integrated Summary of Safety, 90-day Safety Update, data analyses)

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Table of Contents

Table of Contents.....	2
1 Organization of material	9
2 Safety data analyses (tables, figures and listings)	10
Table 1-2-1 Randomized treatment exposure, summary of cycles (FAS safety set)	11
Table 1-2-1s Study treatment exposure, summary of cycles (Sub-study safety analysis set)	13
Table 1-2-1-1s 177Lu-PSMA-617 exposure, summary of cycles (Sub-study safety analysis set)	14
Table 1-2-2s Extent of 177Lu-PSMA-617 exposure by cycle and overall (Sub-study safety analysis set)	15
Table 1-2-3s 177Lu-PSMA-617 treatment exposure, dose adjustments by cycle and overall (Sub-study safety analysis set)	17
Table 1-2-4s Number of Lu-PSMA-617 injections by methods of administration (Sub-study safety analysis set)	19
Table 1-2-5 Best supportive/best standard of care exposure, summary of cycles (FAS safety set)	20
Table 1-2-5s Best supportive/best standard of care exposure, summary of cycles (Sub-study safety analysis set)	22
Table 1-2-6 Novel androgen axis drugs (NAADs) indicated as study best supportive/best standard of care (FAS safety set)	23
Table 1-2-6s Novel androgen axis drugs (NAADs) indicated as study best supportive/best standard of care (Sub-study safety analysis set)	24
Table 1-2-7 Patient disposition - end of treatment and end of study status (Full analysis set)	25
Table 1-2-7s Patient disposition - end of treatment and end of study status (Sub-study safety analysis set)	31
Table 1-2-8 Patient disposition - end of treatment and end of study status (FAS safety set)	34
Table 1-3-1s Demographic and baseline characteristics (Sub-study safety analysis set)	35
Table 1-3-2s Baseline disease characteristics (Sub-study safety analysis set)	37
Table 1-3-3s Non-active medical history (Sub-study safety analysis set)	40
Table 1-3-4s Prior cancer-related surgery (Sub-study safety analysis set)	42
Table 1-3-5s Prior cancer-related radiotherapy (Sub-study safety analysis set)	43
Table 1-3-6s Prior cancer-related systemic therapy - all therapies (Sub-study safety analysis set)	44

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)	46
Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)	174
Table 1-3-8 Concurrent radiotherapy (FAS safety set)	196
Table 1-3-8s Concurrent radiotherapy (Sub-study safety analysis set)	197
Table 1-3-9 Concurrent surgical and therapeutic procedures (FAS safety set)	198
Table 1-3-9s Concurrent surgical and therapeutic procedures (Sub-study safety analysis set)	205
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)	208
Table 1-3-10s Concomitant medications indicated as study best supportive/best standard of care (Sub-study safety analysis set)	220
Table 1-3-11 Concurrent radiotherapy indicated as study best supportive/best standard of care (FAS safety set)	224
Table 1-3-11s Concurrent radiotherapy indicated as study best supportive/best standard of care (Sub-study safety analysis set)	225
Table 1-3-12 Concurrent procedures other than radiotherapy indicated as study best supportive/best standard of care (FAS safety set)	226
Table 1-3-12s Concurrent procedures other than radiotherapy indicated as study best supportive/best standard of care (Sub-study safety analysis set)	227
Table 2-1-1-1 Overview of randomized treatment-emergent adverse events (FAS safety set)	228
Table 2-1-1-1s Overview of study treatment-emergent adverse events (Sub-study safety analysis set)	229
Table 2-1-1-2 Randomized treatment-emergent adverse events by system organ class (FAS safety set)	230
Table 2-1-1-2s Study treatment-emergent adverse events by system organ class (Sub-study safety analysis set)	233
Table 2-1-1-3 Randomized treatment-emergent adverse events by preferred term (FAS safety set)	234
Table 2-1-1-3s Study treatment-emergent adverse events by preferred term (Sub-study safety analysis set)	265
Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)	269
Table 2-1-1-5 Randomized drug-related treatment-emergent adverse events by preferred term (FAS safety set)	343
Table 2-1-1-5s Study drug-related treatment-emergent adverse events by preferred term (Sub-study safety analysis set)	355

Table 2-1-1-6 Overview of adverse events during long-term follow-up (FAS safety set)	357
Table 2-1-1-7 Adverse events during long-term follow-up by preferred term (FAS safety set)	358
Table 2-1-2-1 All deaths (FAS safety set)	370
Table 2-1-2-1s All deaths (Sub-study safety analysis set)	371
Table 2-1-2-2 On-treatment deaths (FAS safety set)	372
Table 2-1-2-2s On-treatment deaths (Sub-study safety analysis set)	373
Table 2-1-2-3 Randomized serious treatment-emergent adverse events leading to fatal outcome (FAS safety set)	374
Table 2-1-2-3s Serious study treatment-emergent adverse events leading to fatal outcome (Sub-study safety analysis set)	376
Table 2-1-2-4 Adverse events during long-term follow-up leading to fatal outcome (FAS safety set)	377
Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)	378
Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)	485
Table 2-1-3-2 Randomized serious treatment-emergent adverse events by preferred term (FAS safety set)	497
Table 2-1-3-2s Serious study treatment-emergent adverse events by preferred term (Sub-study safety analysis set)	507
Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)	508
Table 2-1-3-3s Serious drug-related study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)	540
Table 2-1-4-1s Study treatment-emergent adverse events leading to permanent discontinuation of 177Lu-PSMA-617 by preferred term (Sub-study safety analysis set)	542
Table 2-1-4-2 Randomized treatment-emergent adverse events leading to permanent discontinuation of BSC/BSoC by preferred term (FAS safety set)	543
Table 2-1-4-2s Study treatment-emergent adverse events leading to permanent discontinuation of BSC/BSoC by preferred term (Sub-study safety analysis set)	547
Table 2-1-4-3s Study treatment-emergent adverse events leading to interruption of 177Lu-PSMA-617 by preferred term (Sub-study safety analysis set)	548

Table 2-1-4-4s Study treatment-emergent adverse events leading to reduction of 177Lu-PSMA-617 by preferred term (Sub-study safety analysis set)	549
Table 2-1-4-5 Randomized treatment-emergent adverse events leading to interruption of BSC/BSoC by preferred term (FAS safety set)	550
Table 2-1-4-5s Study treatment-emergent adverse events leading to interruption of BSC/BSoC by preferred term (Sub-study safety analysis set)	554
Table 2-1-4-6 Randomized treatment-emergent adverse events leading to reduction of BSC/BSoC by preferred term (FAS safety set)	555
Table 2-1-4-6s Study treatment-emergent adverse events leading to reduction of BSC/BSoC by preferred term (Sub-study safety analysis set)	557
Table 2-1-5-1 Overview of randomized treatment-emergent safety topics of interest (FAS safety set)	558
Table 2-1-5-1s Overview of study treatment-emergent safety topics of interest (Sub-study safety analysis set)	559
Table 2-1-5-2 Incidence of randomized treatment-emergent safety topics of interest (FAS safety set)	560
Table 2-1-5-2s Incidence of study treatment-emergent safety topics of interest (Sub-study safety analysis set)	574
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)	582
Table 2-1-5-3s Incidence of study treatment-emergent safety topics of interest including preferred term level (Sub-study safety analysis set)	614
Table 2-1-5-4 Time to first occurrence of safety topic of interest (FAS safety set)	630
Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)	634
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)	656
Table 2-1-5-6s Incidence of safety topics of interest during long term follow-up including preferred term level (Sub-study safety analysis set)	666
Table 2-1-7-1 Adverse drug reactions - randomized treatment-emergent adverse events regardless of study drug relationship, by primary system organ class and ADR group (FAS safety set)	667
Table 3-2-1-1 Worst post-baseline hematology abnormalities during randomized treatment based on CTC grades (FAS safety set)	669
Table 3-2-1-1s Worst post-baseline hematology abnormalities during study treatment based on CTC grades (Sub-study safety analysis set)	670
Table 3-2-1-2 Hematology shift table during randomized treatment based on CTC grades (FAS safety set)	671
Table 3-2-1-2s Hematology shift table during study treatment based on CTC grades (Sub-study safety analysis set)	679

Table 3-2-1-3 Worst post-baseline hematology abnormalities during long-term follow up based on CTC grades (FAS safety set)	682
Table 3-2-2-1 Worst post-baseline chemistry abnormalities during randomized treatment based on CTC grades (FAS safety set)	683
Table 3-2-2-1s Worst post-baseline chemistry abnormalities during study treatment based on CTC grades (Sub-study safety analysis set)	684
Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)	685
Table 3-2-2-2s Chemistry shift table during study treatment based on CTC grades (Sub-study safety analysis set)	699
Table 3-2-2-3 Worst post-baseline chemistry abnormalities during long-term follow up based on CTC grades (FAS safety set)	704
Table 3-2-2-4 Categorical analysis of hepatic laboratory values during randomized treatment (FAS safety set)	705
Table 3-2-2-4s Categorical analysis of hepatic laboratory values during study treatment (Sub-study safety analysis set)	706
Table 3-2-2-5 Categorical analysis of hepatic laboratory values during long-term follow up (FAS safety set)	707
Table 3-2-2-6 Serum testosterone shift table during randomized treatment based on normal ranges (FAS safety set)	708
Table 3-2-2-6s Serum testosterone shift table during study treatment based on normal ranges (Sub-study safety analysis set)	709
Table 4-1-1 Notable vital signs during randomized treatment (FAS safety set)	710
Table 4-1-1s Notable vital signs during study treatment (Sub-study safety analysis set)	711
Table A2-1 Adverse drug reactions - randomized treatment-emergent adverse events regardless of study drug relationship, by primary system organ class and ADR group (FAS safety set)	712
Table A2-2 Adverse drug reactions - randomized treatment-emergent adverse events regardless of study drug relationship, by ADR group and preferred term (FAS safety set)	714
Table A2-3 Time to first occurrence of adverse drug reaction (FAS safety set)	717
Table A2-4 Time to first occurrence of grade ≥ 3 adverse drug reaction (FAS safety set)	726
Table A2-5 Incidence of randomized treatment-emergent adverse drug reactions (FAS safety set)	735
Table A2-6 Worsening from baseline - worst hematology abnormalities based on CTCAE grades and frequency category - Lu-PSMA-617+BSC/BSoC arm (FAS safety set)	749

Table A2-7 Worsening from baseline - worst biochemistry abnormalities based on CTCAE grades and frequency category - Lu-PSMA-617+BSC/BSoC arm (FAS safety set)	750
Table A2-8 Worsening from baseline - worst hematology abnormalities based on CTCAE grades and frequency category - BSC/BSoC only arm (FAS safety set)	751
Table A2-9 Worsening from baseline - worst biochemistry abnormalities based on CTCAE grades and frequency category - BSC/BSoC only arm (FAS safety set)	752
Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)	753
Listing 1-2-1 Subject disposition (FAS safety set)	767
Listing 1-2-1s Subject disposition (Sub-study safety analysis set)	851
Listing 1-2-2s 177Lu-PSMA-617 administration (Sub-study safety analysis set)	855
Listing 1-2-3s 177Lu-PSMA-617 administration - dose intensity (Sub-study safety analysis set)	876
Listing 1-3-1s Demographics and baseline characteristics (Sub-study safety analysis set)	877
Listing 1-3-2s Disease characteristics (Sub-study safety analysis set)	880
Listing 1-3-3s Prior prostate cancer-related surgery (Sub-study safety analysis set)	885
Listing 1-3-4s Prior prostate cancer-related radiotherapy (Sub-study safety analysis set)	889
Listing 1-3-5s Prior cancer-related systemic therapy (Sub-study safety analysis set)	893
Listing 1-3-6 Prior and concomitant medications (FAS safety set)	912
Listing 1-3-6s Prior and concomitant medications (Sub-study safety analysis set)	2399
Listing 1-3-7 Surgical and therapeutic procedures other than radiotherapy (FAS safety set)	2467
Listing 1-3-7s Surgical and therapeutic procedures other than radiotherapy (Sub-study safety analysis set)	2540
Listing 1-3-8 Concurrent radiotherapy (FAS safety set)	2554
Listing 1-3-8s Concurrent radiotherapy (Sub-study safety analysis set)	2576
Listing 2-1-1 Randomized treatment adverse events (FAS safety set)	2577
Listing 2-1-1s Study treatment adverse events (Sub-study safety analysis set)	3918
Listing 2-1-2 Randomized treatment serious adverse events (FAS safety set)	3958
Listing 2-1-2s Study treatment serious adverse events (Sub-study safety analysis set)	4049

Listing 2-1-3 Randomized treatment adverse events leading to discontinuation (FAS safety set)	4054
Listing 2-1-3s Study treatment adverse events leading to discontinuation (Sub-study safety analysis set)	4088
Listing 2-1-4 Randomized treatment adverse events leading to reduction and/or interruption (FAS safety set)	4089
Listing 2-1-4s Study treatment adverse events leading to reduction and/or interruption (Sub-study safety analysis set)	4152
Listing 2-1-5 Long term follow-up adverse events (FAS safety set)	4155
Listing 2-1-5s Long term follow-up adverse events (Sub-study safety analysis set)	4288
Listing 2-1-6 Randomized treatment safety topics of interest (FAS safety set)	4289
Listing 2-1-6s Study treatment safety topics of interest (Sub-study safety analysis set)	4893
Listing 2-1-7 Case retrieval strategy for SCS	4914
Listing 2-1-8 Case retrieval strategy for ADR	5112
Listing 2-1-9 Deaths (FAS safety set)	5119
Listing 2-1-9s Deaths (Sub-study safety analysis set)	5179
Listing 3-2-1 Laboratory values - chemistry (FAS safety set).....	5180
Listing 3-2-1s Laboratory values - chemistry (Sub-study safety analysis set)	14866
Listing 3-2-2 Laboratory values - testosterone (FAS safety set)	15240
Listing 3-2-2s Laboratory values - testosterone (Sub-study safety analysis set)	15533
Listing 3-2-3 Laboratory values - hematology (FAS safety set).....	15544
Listing 3-2-3s Laboratory values - hematology (Sub-study safety analysis set)	23095
Listing 3-2-4 Laboratory values - urinalysis (FAS safety set)	23422
Listing 3-2-4s Laboratory values - urinalysis (Sub-study safety analysis set)	24041

1 Organization of material

SCS Appendix 1 contains updated data (based on 28-Jun-2021 data cut-off) from of Study PSMA-617-01 (VISION) that supports the text portion of the Summary of Clinical Safety (SCS) 90-day Safety Update in addition to the data (based on 27-Jan-2021 data cut-off) that was included in the initial SCS.

This appendix includes updated data from the randomized part of the VISION study. It also presents safety data from the VISION sub-study that was not part of the initial SCS.

The initial SCS presented data from VISION randomized part of the study and from Study PSMA-617-02 (RESIST) separately. No pooling was performed. RESIST was completed at the time of the initial submission and therefore no updated data is available. This safety update will present the updated data from the same 734 patients randomized in VISION and, separately, the safety data from the 30 patients enrolled in the sub-study cohort.

Selected listings from the VISION Clinical Study Report and figures, tables and listings from the original SCS Appendix 1 were generated based on the new cut-off date (28-Jun-2021) and organized as per initial SCS.

The material is presented as tables, figures, and listings. New outputs presenting the VISION sub-study data have been numbered with an ‘-s’ suffix.

2 Safety data analyses (tables, figures and listings)

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177Lu-PSMA-617 SCS update

Final Version

Table 1-2-1 Randomized treatment exposure, summary of cycles (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Duration of exposure (months)			
n	529	205	734
Mean	8.50	3.56	7.12
SD	5.244	4.350	5.476
Median	7.82	2.07	5.55
Min-Max	0.3-31.5	0.0-30.9	0.0-31.5
Number of cycles started by patient			
n	529	205	734
Mean	5.7	2.7	4.9
SD	3.22	2.32	3.28
Median	5.0	2.0	4.0
Min-Max	1-16	1-16	1-16
Number of cycles started by patient, n (%)			
n	529	205	734
1 cycle	26 (4.9)	67 (32.7)	93 (12.7)
2 cycles	56 (10.6)	65 (31.7)	121 (16.5)
3 cycles	76 (14.4)	28 (13.7)	104 (14.2)
4 cycles	71 (13.4)	13 (6.3)	84 (11.4)
5 cycles	43 (8.1)	13 (6.3)	56 (7.6)
6 cycles	53 (10.0)	4 (2.0)	57 (7.8)
7 cycles	60 (11.3)	5 (2.4)	65 (8.9)
8 cycles	51 (9.6)	3 (1.5)	54 (7.4)
9 cycles	27 (5.1)	2 (1.0)	29 (4.0)
10 cycles	20 (3.8)	2 (1.0)	22 (3.0)
11 cycles	13 (2.5)	0	13 (1.8)
12 cycles	11 (2.1)	1 (0.5)	12 (1.6)
13 cycles	12 (2.3)	1 (0.5)	13 (1.8)
14 cycles	4 (0.8)	0	4 (0.5)
15 cycles	2 (0.4)	0	2 (0.3)
16 cycles	4 (0.8)	1 (0.5)	5 (0.7)
Average duration of treatment cycles (months)			
n	529	205	734
Mean	1.43	1.09	1.34
SD	0.256	0.345	0.321
Median	1.38	1.12	1.37
Min-Max	0.2-2.4	0.0-2.1	0.0-2.4
Patients with at least one cycle delayed, n (%)			
n	162 (30.6)	16 (7.8)	178 (24.3)
Number of cycles delayed			
n	162	16	178
Mean	1.4	1.4	1.4
SD	0.77	0.81	0.77
Median	1.0	1.0	1.0
Min-Max	1-5	1-4	1-5
Reason for delay of cycle(s), n (%)			
Delayed due to adverse event	45 (8.5)	4 (2.0)	49 (6.7)
Delayed due to scheduling purposes	124 (23.4)	13 (6.3)	137 (18.7)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update	Final Version	
Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)

A patient may be counted in more than one row for reason for delay of cycle.

Cycle visits are scheduled every 6 weeks for the first 6 cycles and then every 12 weeks after cycle 6.

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Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-2-1s Study treatment exposure, summary of cycles (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30)
Duration of exposure (months)	
n	30
Mean	5.81
SD	2.196
Median	5.73
Min-Max	1.4-9.0
Number of cycles started by patient	
n	30
Mean	4.4
SD	1.90
Median	4.0
Min-Max	1-9
Number of cycles started by patient, n (%)	
n	30
1 cycle	1 (3.3)
2 cycles	5 (16.7)
3 cycles	4 (13.3)
4 cycles	7 (23.3)
5 cycles	4 (13.3)
6 cycles	5 (16.7)
7 cycles	3 (10.0)
8 cycles	0
9 cycles	1 (3.3)
Average duration of treatment cycles (months)	
n	30
Mean	1.29
SD	0.241
Median	1.38
Min-Max	0.4-1.7
Patients with at least one cycle delayed, n (%)	
	1 (3.3)
Number of cycles delayed	
n	1
Mean	1.0
SD	NE
Median	1.0
Min-Max	1-1
Reason for delay of cycle(s), n (%)	
Delayed due to adverse event	1 (3.3)
Delayed due to scheduling purposes	0

A patient may be counted in more than one row for reason for delay of cycle.

Cycle visits are scheduled every 6 weeks for the first 6 cycles and then every 12 weeks after cycle 6. Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

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177Lu-PSMA-617 SCS update

Final Version

Table 1-2-1-1s 177Lu-PSMA-617 exposure, summary of cycles (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30)
Duration of exposure (months)	
n	30
Mean	5.60
SD	2.150
Median	5.52
Min-Max	1.4-9.0
Number of cycles started by patient	
n	30
Mean	4.0
SD	1.47
Median	4.0
Min-Max	1-6
Number of cycles started by patient, n (%)	
n	30
1 cycle	1 (3.3)
2 cycles	5 (16.7)
3 cycles	4 (13.3)
4 cycles	8 (26.7)
5 cycles	6 (20.0)
6 cycles	6 (20.0)
Average duration of treatment cycles (months)	
n	30
Mean	1.37
SD	0.117
Median	1.37
Min-Max	1.0-1.7
Patients with at least one cycle delayed, n (%)	1 (3.3)
Number of cycles delayed	
n	1
Mean	1.0
SD	NE
Median	1.0
Min-Max	1-1
Reason for delay of cycle(s), n (%)	
Delayed due to adverse event	1 (3.3)
Delayed due to scheduling purposes	0

A patient may be counted in more than one row for reason for delay of cycle.
177Lu-PSMA-617 cycles are once every 6 weeks for a maximum of 6 cycles.
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Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-2-2s Extent of 177Lu-PSMA-617 exposure by cycle and overall (Sub-study safety analysis set)

		Statistics	Lu-PSMA-617 +BSC/BSoC (N=30)
Overall		Cumulative dose (GBq)	n 30 Mean 28.73 SD 10.514 Median 28.74 Min-Max 7.2-44.6
		Dose intensity (GBq/month)	n 30 Mean 5.26 SD 0.588 Median 5.18 Min-Max 4.5-7.5
		Relative dose intensity (%)	n 30 Mean 100.13 SD 9.386 Median 98.49 Min-Max 91.3-141.1
Cycle 1	Dose intensity per cycle (GBq/cycle)	n 30 Mean 7.13 SD 0.203 Median 7.12 Min-Max 6.7-7.5	
	Relative cycle dose intensity (%)	n 30 Mean 96.30 SD 2.748 Median 96.20 Min-Max 90.0-101.6	
Cycle 2	Dose intensity per cycle (GBq/cycle)	n 29 Mean 7.22 SD 0.361 Median 7.31 Min-Max 6.0-7.8	
	Relative cycle dose intensity (%)	n 29 Mean 98.24 SD 3.884 Median 98.92 Min-Max 90.8-105.1	
Cycle 3	Dose intensity per cycle (GBq/cycle)	n 24 Mean 7.14 SD 0.425 Median 7.19 Min-Max 5.6-7.7	
	Relative cycle dose intensity (%)	n 24 Mean 97.33 SD 3.735 Median 97.14 Min-Max 90.8-104.1	
Cycle 4	Dose intensity per cycle (GBq/cycle)	n 20	

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update		Final Version
		Lu-PSMA-617 +BSC/BSoC (N=30)
Cycle 5	Relative cycle dose intensity (%)	Statistics
	Mean	7.06
	SD	0.419
	Median	7.14
	Min-Max	6.0-7.6
Cycle 5	Dose intensity per cycle (GBq/cycle)	Statistics
	n	20
	Mean	96.42
	SD	4.691
	Median	97.58
Cycle 5	Relative cycle dose intensity (%)	Statistics
	n	12
	Mean	95.62
	SD	5.454
	Median	96.74
Cycle 6	Relative cycle dose intensity (%)	Statistics
	n	12
	Mean	95.62
	SD	5.454
	Median	96.74
Cycle 6	Dose intensity per cycle (GBq/cycle)	Statistics
	n	6
	Mean	7.12
	SD	0.286
	Median	7.05
Cycle 6	Relative cycle dose intensity (%)	Statistics
	n	6
	Mean	96.25
	SD	3.871
	Median	95.24
	Min-Max	91.9-101.9

177Lu-PSMA-617 cycles are once every 6 weeks for a maximum of 6 cycles

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Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-2-3s 177Lu-PSMA-617 treatment exposure, dose adjustments by cycle and overall (Sub-study safety analysis set)

		Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Overall	Number of patients with at least one dose interrupted	0
	Number of patients with at least one dose interrupted by reason	
	Adverse event	0
	Administration issue	0
	Other	0
	Number of patients with at least one dose reduced (due to AE)	2 (6.7)
Cycle 1	Number of patients with at least one dose interrupted	0
	Number of patients with at least one dose interrupted by reason	
	Adverse event	0
	Administration issue	0
	Other	0
	Number of patients with at least one dose reduced (due to AE)	0
Cycle 2	Number of patients with at least one dose interrupted	0
	Number of patients with at least one dose interrupted by reason	
	Adverse event	0
	Administration issue	0
	Other	0
	Number of patients with at least one dose reduced (due to AE)	0
Cycle 3	Number of patients with at least one dose interrupted	0
	Number of patients with at least one dose interrupted by reason	
	Adverse event	0
	Administration issue	0
	Other	0
	Number of patients with at least one dose reduced (due to AE)	0
Cycle 4	Number of patients with at least one dose interrupted	0
	Number of patients with at least one dose interrupted by reason	
	Adverse event	0
	Administration issue	0
	Other	0
	Number of patients with at least one dose reduced (due to AE)	0
Cycle 5	Number of patients with at least one dose interrupted	0
	Number of patients with at least one dose interrupted by reason	
	Adverse event	0
	Administration issue	0
	Other	0
	Number of patients with at least one dose reduced (due to AE)	0
Cycle 6	Number of patients with at least one dose interrupted	0
	Number of patients with at least one dose interrupted by reason	
	Adverse event	0
	Administration issue	0
	Number of patients with at least one dose reduced (due to AE)	1 (3.3)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)
n (%)

Other

0

Number of patients with at least one dose reduced (due to AE)

0

177Lu-PSMA-617 cycles are once every 6 weeks for a maximum of 6 cycles

Output ID: T-1-2-3s 2021-09-22 16:53

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-expo-adj.sas

Source data: adsl.xpt, adex.xpt, adex.xpt

Data Cutoff Date: 28JUN2021

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177Lu-PSMA-617 SCS update

Final Version

Table 1-2-4s Number of Lu-PSMA-617 injections by methods of administration (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Total number of administrations	121
Number of administrations by Gravity Method	4 (3.3)
Number of administrations by Syringe with or without Pump	115 (95.0)
Number of administrations by Vial with Pump	2 (1.7)

Percentages are based on total number of administrations

Source data is the SDTM EC and SUPPEC domains

Output ID: T-1-2-4s 2021-09-22 16:36

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\

PGM\\t-admethod.sas

Source data: ec.xpt suppec.xpt , adsl.xpt

Data Cutoff Date: 28JUN2021

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177Lu-PSMA-617 SCS update

Final Version

Table 1-2-5 Best supportive/best standard of care exposure, summary of cycles (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Duration of exposure (months)			
n	529	205	734
Mean	9.18	3.56	7.61
SD	6.583	4.350	6.546
Median	7.56	2.07	5.55
Min-Max	0.3-33.2	0.0-30.9	0.0-33.2
Number of cycles started by patient			
n	529	205	734
Mean	5.7	2.7	4.9
SD	3.23	2.32	3.28
Median	5.0	2.0	4.0
Min-Max	1-16	1-16	1-16
Number of cycles started by patient, n (%)			
n	529	205	734
1 cycle	27 (5.1)	67 (32.7)	94 (12.8)
2 cycles	57 (10.8)	65 (31.7)	122 (16.6)
3 cycles	77 (14.6)	28 (13.7)	105 (14.3)
4 cycles	70 (13.2)	13 (6.3)	83 (11.3)
5 cycles	43 (8.1)	13 (6.3)	56 (7.6)
6 cycles	51 (9.6)	4 (2.0)	55 (7.5)
7 cycles	61 (11.5)	5 (2.4)	66 (9.0)
8 cycles	50 (9.5)	3 (1.5)	53 (7.2)
9 cycles	27 (5.1)	2 (1.0)	29 (4.0)
10 cycles	20 (3.8)	2 (1.0)	22 (3.0)
11 cycles	13 (2.5)	0	13 (1.8)
12 cycles	12 (2.3)	1 (0.5)	13 (1.8)
13 cycles	11 (2.1)	1 (0.5)	12 (1.6)
14 cycles	4 (0.8)	0	4 (0.5)
15 cycles	2 (0.4)	0	2 (0.3)
16 cycles	4 (0.8)	1 (0.5)	5 (0.7)
Average duration of treatment cycles (months)			
n	529	205	734
Mean	1.42	1.09	1.33
SD	0.264	0.345	0.325
Median	1.38	1.12	1.37
Min-Max	0.2-2.4	0.0-2.1	0.0-2.4
Patients with at least one cycle delayed, n (%)			
	162 (30.6)	16 (7.8)	178 (24.3)
Number of cycles delayed			
n	162	16	178
Mean	1.4	1.4	1.4
SD	0.77	0.81	0.77
Median	1.0	1.0	1.0
Min-Max	1-5	1-4	1-5
Reason for delay of cycle(s), n (%)			
Delayed due to adverse event	45 (8.5)	4 (2.0)	49 (6.7)
Delayed due to scheduling purposes	124 (23.4)	13 (6.3)	137 (18.7)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update	Final Version	
Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)

A patient may be counted in more than one row for reason for delay of cycle.

Cycle visits are scheduled every 6 weeks for the first 6 cycles and then every 12 weeks after cycle 6.

Output ID: T-1-2-5 2021-09-22 16:52

...BIOMETRY\PROJECTS\PSMA617\VISION\SAFETY_UPDATE_90DAYS\PRODUCTION\TLFPGM\it-expo.sas

Source data: adsl.xpt, adex.xpt

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177Lu-PSMA-617 SCS update
Table 1-2-5s Best supportive/best standard of care exposure, summary of cycles (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30)
Duration of exposure (months)	
n	30
Mean	5.95
SD	2.776
Median	5.96
Min-Max	0.4-14.3
Number of cycles started by patient	
n	30
Mean	4.4
SD	1.90
Median	4.0
Min-Max	1-9
Number of cycles started by patient, n (%)	
n	30
1 cycle	1 (3.3)
2 cycles	5 (16.7)
3 cycles	4 (13.3)
4 cycles	7 (23.3)
5 cycles	4 (13.3)
6 cycles	5 (16.7)
7 cycles	3 (10.0)
8 cycles	0
9 cycles	1 (3.3)
Average duration of treatment cycles (months)	
n	30
Mean	1.32
SD	0.237
Median	1.38
Min-Max	0.4-1.7
Patients with at least one cycle delayed, n (%)	
Number of cycles delayed	
n	1
Mean	1.0
SD	NE
Median	1.0
Min-Max	1-1
Reason for delay of cycle(s), n (%)	
Delayed due to adverse event	1 (3.3)
Delayed due to scheduling purposes	0

A patient may be counted in more than one row for reason for delay of cycle.
Cycle visits are scheduled every 6 weeks for the first 6 cycles and then every 12 weeks after cycle 6.
Output ID: T-1-2-5s 2021-09-22 16:53
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ION\\TLF\\PGM\\t-expo.sas
Source data: adsl.xpt, adex.xpt
Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-2-6 Novel androgen axis drugs (NAADs) indicated as study best supportive/best standard of care (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Number of patients with at least one NAAD indicated as study BSC/BSoC, n (%)	278 (52.6)	139 (67.8)	417 (56.8)
Type of NAAD, n (%)			
ENZALUTAMIDE	157 (29.7)	88 (42.9)	245 (33.4)
ABIRATERONE	132 (25.0)	72 (35.1)	204 (27.8)
APALUTAMIDE	10 (1.9)	1 (0.5)	11 (1.5)
DAROLUTAMIDE	2 (0.4)	1 (0.5)	3 (0.4)
Duration of exposure to NAAD as study BSC/BSoC (months)			
n	278	139	417
Mean	8.59	3.75	6.98
SD	6.930	4.853	6.709
Median	6.59	2.07	4.47
Min-Max	0.0-33.2	0.1-30.9	0.0-33.2

Preferred terms are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.
Every patient is counted a single time for each type of NAAD.

NAADs indicated as BSC/BSoC are all NAAD medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHODrug Global version Mar 2021 B3.

Output ID: T-1-2-6 2021-09-22 17:01

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-naad.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-2-6s Novel androgen axis drugs (NAADs) indicated as study best supportive/best standard of care (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30)
Number of patients with at least one NAAD indicated as study BSC/BSoC, n (%)	12 (40.0)
Type of NAAD, n (%)	
ENZALUTAMIDE	10 (33.3)
ABIRATERONE	2 (6.7)
Duration of exposure to NAAD as study BSC/BSoC (months)	
n	12
Mean	5.72
SD	2.813
Median	6.77
Min-Max	0.4-9.2

Preferred terms are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each type of NAAD.

NAADs indicated as BSC/BSoC are all NAAD medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-2-6s 2021-09-22 17:01

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ION\\TLF\\PGM\\t-naad.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-2-7 Patient disposition - end of treatment and end of study status (Full analysis set)

	Lu-PSMA-617 +BSC/BSoc (N=551)	BSC/BSoC only (N=280)	Overall (N=831)
Patients treated	533 (96.7)	201 (71.8)	734 (88.3)
Patients not treated	18 (3.3)	79 (28.2)	97 (11.7)
Patients still on treatment ^a	25 (4.5)	1 (0.4)	26 (3.1)
Patients who discontinued from all study treatments	508 (92.2)	200 (71.4)	708 (85.2)
Patients treated with 177Lu-PSMA-617	529 (96.0)		
Patients not treated with 177Lu-PSMA-617	22 (4.0)		
Reason not treated with 177Lu-PSMA-617			
Adverse event	6 (1.1)		
Investigator decision	3 (0.5)		
No longer clinically benefitting	3 (0.5)		
Withdrew consent (treatment)	3 (0.5)		
Death	2 (0.4)		
Other	2 (0.4)		
Protocol deviation	2 (0.4)		
Progressive disease	1 (0.2)		
Reason for withdrew consent from 177Lu-PSMA-617			
No reason given	1 (0.2)		
Reason is not provided	1 (0.2)		
Treatment "fatigue" due to travel or protocol procedures	1 (0.2)		
Time to withdrew consent from 177Lu-PSMA-617 (days)			
n	3		
Mean	26.0		
SD	10.54		
Median	25.0		
Min-Max	16-37		
Time to withdrew consent from 177Lu-PSMA-617 (days category), n (%)			
n	3		
1	0		
2 - 28	2 (66.7)		

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=551)	BSC/BSoC only (N=280)	Overall (N=831)
29 - 56	1 (33.3)	0	
>56			
Patients who completed 177Lu-PSMA-617	250 (45.4)		
Patients who discontinued from 177Lu-PSMA-617	279 (50.6)		
Reason for discontinuation from 177Lu-PSMA-617			
Progressive disease	127 (23.0)		
Adverse event	54 (9.8)		
No longer clinically benefitting	36 (6.5)		
Withdrew consent (treatment)	23 (4.2)		
Investigator decision	16 (2.9)		
Death	14 (2.5)		
Patient requires care not allowed in the study	6 (1.1)		
Other	2 (0.4)		
Subject lost to follow-up	1 (0.2)		
Reason for withdrew consent from 177Lu-PSMA-617			
Decided to pursue off-study treatment	7 (1.3)		
Perceived lack of benefit	6 (1.1)		
Treatment "fatigue" due to travel or protocol procedures	5 (0.9)		
No reason given	4 (0.7)		
Reason is not provided	1 (0.2)		
Time to withdrew consent from 177Lu-PSMA-617 (days)			
n	23		
Mean	145.0		
SD	72.02		
Median	159.0		
Min-Max	30-327		
Time to withdrew consent from 177Lu-PSMA-617 (days category), n (%)			
n	23		
1	0		
2 - 28	0		
29 - 56	3 (13.0)		
>56	20 (87.0)		

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=551)	BSC/BSoC only (N=280)	Overall (N=831)
Patients treated with BSC/BSoC	533 (96.7)	201 (71.8)	734 (88.3)
Patients not treated with BSC/BSoC	18 (3.3)	79 (28.2)	97 (11.7)
Reason not treated with BSC/BSoC			
Adverse event	5 (0.9)	0	5 (0.6)
Death	2 (0.4)	3 (1.1)	5 (0.6)
Investigator decision	2 (0.4)	1 (0.4)	3 (0.4)
No longer clinically benefitting	2 (0.4)	5 (1.8)	7 (0.8)
Other	2 (0.4)	3 (1.1)	5 (0.6)
Protocol deviation	2 (0.4)	0	2 (0.2)
Withdrew consent (treatment)	2 (0.4)	46 (16.4)	48 (5.8)
Progressive disease	1 (0.2)	1 (0.4)	2 (0.2)
Patient requires care not allowed in the study	0	16 (5.7)	16 (1.9)
Subject lost to follow-up	0	4 (1.4)	4 (0.5)
Reason for withdrew consent from BSC/BSoC			
No reason given	1 (0.2)	7 (2.5)	8 (1.0)
Treatment "fatigue" due to travel or protocol procedures	1 (0.2)	2 (0.7)	3 (0.4)
Because receiving best supportive care without 177Lu-PSMA-617	0	31 (11.1)	31 (3.7)
Decided to pursue off-study treatment	0	5 (1.8)	5 (0.6)
Perceived lack of benefit	0	1 (0.4)	1 (0.1)
Time to withdrew consent from BSC/BSoC (days)			
n	2	46	48
Mean	20.5	13.8	14.1
SD	6.36	20.55	20.18
Median	20.5	8.0	9.0
Min-Max	16-25	1-97	1-97
Time to withdrew consent from BSC/BSoC (days category), n (%)			
n	2	46	48
1	0	8 (17.4)	8 (16.7)
2 - 28	2 (100)	32 (69.6)	34 (70.8)
29 - 56	0	4 (8.7)	4 (8.3)
>56	0	2 (4.3)	2 (4.2)
Patients who discontinued from BSC/BSoC	508 (92.2)	200 (71.4)	708 (85.2)

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=551)	BSC/BSoC only (N=280)	Overall (N=831)
Reason for discontinuation from BSC/BSoC			
Progressive disease	234 (42.5)	74 (26.4)	308 (37.1)
No longer clinically benefitting	76 (13.8)	51 (18.2)	127 (15.3)
Withdrew consent (treatment)	52 (9.4)	37 (13.2)	89 (10.7)
Investigator decision	44 (8.0)	10 (3.6)	54 (6.5)
Adverse event	29 (5.3)	4 (1.4)	33 (4.0)
Patient requires care not allowed in the study	28 (5.1)	11 (3.9)	39 (4.7)
Death	27 (4.9)	8 (2.9)	35 (4.2)
Other	13 (2.4)	1 (0.4)	14 (1.7)
Subject non-compliance	4 (0.7)	3 (1.1)	7 (0.8)
Subject lost to follow-up	1 (0.2)	0	1 (0.1)
Protocol deviation	0	1 (0.4)	1 (0.1)
Reason for withdrew consent from BSC/BSoC			
Decided to pursue off-study treatment	14 (2.5)	7 (2.5)	21 (2.5)
Treatment "fatigue" due to travel or protocol procedures	13 (2.4)	8 (2.9)	21 (2.5)
Perceived lack of benefit	11 (2.0)	4 (1.4)	15 (1.8)
No reason given	9 (1.6)	5 (1.8)	14 (1.7)
Because receiving best supportive care without 177Lu-PSMA-617	2 (0.4)	12 (4.3)	14 (1.7)
Reason is not provided	2 (0.4)	0	2 (0.2)
Cannot afford non-medical costs related to the study (travel, etc.)	1 (0.2)	0	1 (0.1)
Cannot afford medical costs related to the study	0	1 (0.4)	1 (0.1)
Time to withdrew consent from BSC/BSoC (days)			
n	52	37	89
Mean	241.4	92.9	179.6
SD	167.20	132.46	169.69
Median	197.0	44.0	138.0
Min-Max	30-974	7-727	7-974
Time to withdrew consent from BSC/BSoC (days category), n (%)			
n	52	37	89
1	0	0	0
2 - 28	0	8 (21.6)	8 (9.0)
29 - 56	5 (9.6)	14 (37.8)	19 (21.3)
>56	47 (90.4)	15 (40.5)	62 (69.7)

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177Lu-PSMA-617 SCS update

	Final Version		
	Lu-PSMA-617 +BSC/BSoc (N=551)	BSC/BSoC only (N=280)	Overall (N=831)
Patients continuing in long-term follow-up period ^b	111 (20.1)	37 (13.2)	148 (17.8)
Patients who discontinued from study	415 (75.3)	242 (86.4)	657 (79.1)
Reason for discontinuation from study			
Death	379 (68.8)	178 (63.6)	557 (67.0)
Withdrew consent (protocol)	31 (5.6)	58 (20.7)	89 (10.7)
Subject lost to follow-up	5 (0.9)	5 (1.8)	10 (1.2)
Investigator decision	0	1 (0.4)	1 (0.1)
Reason for withdrew consent from study			
No reason given	9 (1.6)	10 (3.6)	19 (2.3)
Perceived lack of benefit	8 (1.5)	5 (1.8)	13 (1.6)
Decided to pursue off-study treatment	6 (1.1)	12 (4.3)	18 (2.2)
Treatment "fatigue" due to travel or protocol procedures	6 (1.1)	7 (2.5)	13 (1.6)
Because receiving best supportive care without 177Lu-PSMA-617	1 (0.2)	23 (8.2)	24 (2.9)
Cannot afford non-medical costs related to the study (travel, etc.)	1 (0.2)	0	1 (0.1)
Cannot afford medical costs related to the study	0	1 (0.4)	1 (0.1)
Time to withdrew consent from study (days)			
n	31	58	89
Mean	236.0	109.1	153.3
SD	185.40	185.65	194.27
Median	196.0	25.5	65.0
Min-Max	1-657	1-727	1-727
Time to withdrew consent from study (days category), n (%)			
n	31	58	89
1	1 (3.2)	4 (6.9)	5 (5.6)
2 - 28	1 (3.2)	27 (46.6)	28 (31.5)
29 - 56	3 (9.7)	5 (8.6)	8 (9.0)
>56	26 (83.9)	22 (37.9)	48 (53.9)

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177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617 +BSC/BSoc (N=551)	BSC/BSoC only (N=280)	Overall (N=831)
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Results except for time to withdrew consent (continuous) given as xx (xx.x) where xx=number of patients, (xx.x)=percentage
Time to withdrew consent from treatment (or study) is defined as the time (in days) from the date of randomization to the date of withdrawal of consent from treatment (or study).

^a Patients still on treatment at the time of the data cut-off date 28JUN2021

^b Patients in long-term follow-up period are those that have completed, discontinued treatment or never treated and have not discontinued from the study at the time of the data cut-off date.

Output ID: T-1-2-7 2021-09-22 16:48

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Source data: adsl.xpt

Data Cutoff Date: 28JUN2021

Table 1-2-7s Patient disposition - end of treatment and end of study status (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30)
Patients treated	30 (100)
Patients not treated	0
Patients still on treatment ^a	12 (40.0)
Patients who discontinued from all study treatments	18 (60.0)
Patients treated with 177Lu-PSMA-617	30 (100)
Patients not treated with 177Lu-PSMA-617	0
Patients who completed 177Lu-PSMA-617	6 (20.0)
Patients who discontinued from 177Lu-PSMA-617	20 (66.7)
Reason for discontinuation from 177Lu-PSMA-617	
Progressive disease	7 (23.3)
Investigator decision	4 (13.3)
Adverse event	3 (10.0)
Death	2 (6.7)
Withdrew consent (treatment)	2 (6.7)
No longer clinically benefitting	1 (3.3)
Other	1 (3.3)
Reason for withdrew consent from 177Lu-PSMA-617	
No reason given	1 (3.3)
Treatment "fatigue" due to travel or protocol procedures	1 (3.3)
Time to withdrew consent from 177Lu-PSMA-617 (days)	
n	2
Mean	111.0
SD	63.64
Median	111.0
Min-Max	66-156
Time to withdrew consent from 177Lu-PSMA-617 (days category), n (%)	
n	2
1	0
2 - 28	0

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=30)
29 - 56	0
>56	2 (100)
Patients treated with BSC/BSoC	30 (100)
Patients not treated with BSC/BSoC	0
Patients who discontinued from BSC/BSoC	18 (60.0)
Reason for discontinuation from BSC/BSoC	
Progressive disease	9 (30.0)
Death	5 (16.7)
Withdrew consent (treatment)	2 (6.7)
Adverse event	1 (3.3)
No longer clinically benefitting	1 (3.3)
Reason for withdrew consent from BSC/BSoC	
No reason given	1 (3.3)
Treatment "fatigue" due to travel or protocol procedures	1 (3.3)
Time to withdrew consent from BSC/BSoC (days)	
n	2
Mean	111.0
SD	63.64
Median	111.0
Min-Max	66-156
Time to withdrew consent from BSC/BSoC (days category), n (%)	
n	2
1	0
2 - 28	0
29 - 56	0
>56	2 (100)
Patients continuing in long-term follow-up period ^b	9 (30.0)
Patients who discontinued from study	9 (30.0)
Reason for discontinuation from study	
Death	6 (20.0)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)

Withdrew consent (protocol)	3 (10.0)
Reason for withdrew consent from study	
No reason given	2 (6.7)
Treatment "fatigue" due to travel or protocol procedures	1 (3.3)
Time to withdrew consent from study (days)	
n	3
Mean	111.3
SD	45.00
Median	112.0
Min-Max	66-156
Time to withdrew consent from study (days category), n (%)	
n	3
1	0
2 - 28	0
29 - 56	0
>56	3 (100)

Results except for time to withdrew consent (continuous) given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Time to withdrew consent from treatment (or study) is defined as the time (in days) from the date of study treatment to the date of withdrawal of consent from treatment (or study).

^a Patients still on treatment at the time of the data cut-off date 28JUN2021

^b Patients in long-term follow-up period are those that have completed, discontinued treatment or never treated and have not discontinued from the study at the time of the data cut-off date.

Output ID: T-1-2-7s 2021-09-22 16:50

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Source data: adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-2-8 Patient disposition - end of treatment and end of study status (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Patients treated	529 (100)	205 (100)	734 (100)
Patients still on treatment*	25 (4.7)	1 (0.5)	26 (3.5)
Patients who completed 177Lu-PSMA-617	250 (47.3)		
Patients who discontinued from 177Lu-PSMA-617	279 (52.7)		
Patients who discontinued from BSC/BSoC	504 (95.3)	204 (99.5)	708 (96.5)
Patients who discontinued from all study treatments	504 (95.3)	204 (99.5)	708 (96.5)
Patients who discontinued from study	393 (74.3)	173 (84.4)	566 (77.1)
Reason for discontinuation from 177Lu-PSMA-617			
Progressive disease	127 (24.0)		
Adverse event	54 (10.2)		
No longer clinically benefitting	36 (6.8)		
Withdrew consent (treatment)	23 (4.3)		
Investigator decision	16 (3.0)		
Death	14 (2.6)		
Patient requires care not allowed in the study	6 (1.1)		
Other	2 (0.4)		
Subject lost to follow-up	1 (0.2)		
Reason for discontinuation from BSC/BSoC			
Progressive disease	234 (44.2)	74 (36.1)	308 (42.0)
No longer clinically benefitting	76 (14.4)	51 (24.9)	127 (17.3)
Withdrew consent (treatment)	51 (9.6)	38 (18.5)	89 (12.1)
Investigator decision	42 (7.9)	12 (5.9)	54 (7.4)
Adverse event	29 (5.5)	4 (2.0)	33 (4.5)
Patient requires care not allowed in the study	28 (5.3)	11 (5.4)	39 (5.3)
Death	26 (4.9)	9 (4.4)	35 (4.8)
Other	13 (2.5)	1 (0.5)	14 (1.9)
Subject non-compliance	4 (0.8)	3 (1.5)	7 (1.0)
Subject lost to follow-up	1 (0.2)	0	1 (0.1)
Protocol deviation	0	1 (0.5)	1 (0.1)
Reason for discontinuation from study			
Death	359 (67.9)	143 (69.8)	502 (68.4)
Withdrew consent (protocol)	29 (5.5)	27 (13.2)	56 (7.6)
Subject lost to follow-up	5 (0.9)	2 (1.0)	7 (1.0)
Investigator decision	0	1 (0.5)	1 (0.1)

* Patients still on treatment at the time of the data cut-off date 28JUN2021

Output ID: T-1-2-8 2021-09-22 16:51

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Source data: adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-1s Demographic and baseline characteristics (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30)
Age (years)	
n	30
Mean	66.7
SD	6.94
Median	67.0
Min-Max	52-80
Age (categorized), n (%)	
<65 years	12 (40.0)
=>65 years	18 (60.0)
<65 years	12 (40.0)
=>65-84 years	18 (60.0)
=>85 years	0
Race ^a , n (%)	
White	30 (100)
Black or African American	0
Asian	0
Other	0
Missing	0
Ethnicity, n (%)	
Hispanic or latino	1 (3.3)
Not hispanic or latino	25 (83.3)
Not reported	4 (13.3)
Weight (kg)	
n	30
Mean	89.87
SD	16.922
Median	88.80
Min-Max	63.8-143.0
Height (cm)	
n	30
Mean	177.3
SD	7.93
Median	176.0
Min-Max	163-195
Body Mass Index (kg/m ²)	
n	30
Mean	28.58
SD	4.658
Median	28.41
Min-Max	18.2-38.8
ECOG Performance Status ^b , n (%)	
0-1	28 (93.3)
2	2 (6.7)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)

^a Other includes Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native and more than one race reported.

^b ECOG performance status was not collected at the time of screening and was only captured as the categories 0-1 vs. 2 on the enrollment CRF page.

Output ID: T-1-3-1s 2021-09-22 16:47

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Source data: adsl.xpt

Data Cutoff Date: 28JUN2021

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Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-2s Baseline disease characteristics (Sub-study safety analysis set)Final Version
Lu-PSMA-617+
BSC/BSoC
(N=30)

	Lu-PSMA-617+ BSC/BSoC (N=30)
Time since initial cancer diagnosis (years)	
n	30
Mean	6.74
SD	4.448
Median	6.20
Min-Max	1.6-18.8
Initial histopathological classification, n (%)	
Adenocarcinoma	28 (93.3)
Neuroendocrine	0
Unknown	2 (6.7)
Other	0
Initial histopathological grade, n (%)	
Grade 1	0
Grade 2	5 (16.7)
Grade 3	8 (26.7)
Grade 3-4	0
Grade 4	3 (10.0)
Grade 5	4 (13.3)
Unknown	10 (33.3)
Initial Gleason score, categorized, n (%)	
2-3	0
4-7	9 (30.0)
8-10	19 (63.3)
Unknown	2 (6.7)
Staging at initial diagnosis, n (%)	
I	0
IA	0
IB	0
II	0
IIA	2 (6.7)
IIB	0
III	0
IIIA	2 (6.7)
IIIB	2 (6.7)
IIIC	0
IV	5 (16.7)
IVA	2 (6.7)
IVB	3 (10.0)
Unknown	14 (46.7)
Baseline target lesions, n (%)	
Yes	19 (63.3)
No	11 (36.7)
Baseline non-target lesions, n (%)	
Yes	23 (76.7)
No	7 (23.3)
Total sum of target lesion diameters (mm)	
n	19
Mean	57.1

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617+ BSC/BSoC (N=30)
SD	34.56
Median	49.0
Min-Max	15-136
Site of disease (target and non-target lesions) ^a , n (%)	
Lung	
Yes	3 (10.0)
No	27 (90.0)
Liver	
Yes	3 (10.0)
No	27 (90.0)
Lymph node	
Yes	20 (66.7)
No	10 (33.3)
Bone	
Yes	27 (90.0)
No	3 (10.0)
Baseline PSA doubling time (months) ^b	
n	16
Mean	3.98
SD	4.019
Median	2.23
Min-Max	0.0-12.3
Baseline PSA doubling time (categorized), n (%)	
Stable, non-increasing or decreasing	1 (6.3)
<= 6 months	11 (68.8)
> 6 months	4 (25.0)
Baseline PSA (ng/mL)	
n	30
Mean	140.9
SD	269.23
Median	51.9
Min-Max	3-1399
Baseline ALP (IU/L)	
n	30
Mean	164.1
SD	178.00
Median	96.5
Min-Max	30-692
Baseline LDH (IU/L)	
n	30
Mean	437.5
SD	725.96
Median	258.5
Min-Max	164-4202

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617+
BSC/BSoC
(N=30)

^a Bone site of disease was based on data collected on target and/or non-target lesion or bone scan assessments.

^b Baseline PSA doubling time was derived for each patient as the natural log 2 divided by the sum of the fixed and random slopes of the random coefficient linear model between natural log of PSA and time of PSA measurement (in months). Patients with at least 3 PSA values prior to and at the time of screening were included in the model.

Note: PSA - Prostate Specific Antigen, ALP - Alkaline phosphatase, LDH - Lactate dehydrogenase

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Source data: adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-3s Non-active medical history (Sub-study safety analysis set)

Final Version

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Patients with at least one non-active medical condition/procedure ^a	14 (46.7)
Cardiac disorders	4 (13.3)
Acute myocardial infarction	1 (3.3)
Coronary artery disease	1 (3.3)
Myocardial infarction	1 (3.3)
Pericarditis	1 (3.3)
Infections and infestations	1 (3.3)
COVID-19	1 (3.3)
Injury, poisoning and procedural complications	1 (3.3)
Ligament rupture	1 (3.3)
Musculoskeletal and connective tissue disorders	5 (16.7)
Intervertebral disc protrusion	3 (10.0)
Bone pain	1 (3.3)
Osteitis	1 (3.3)
Nervous system disorders	4 (13.3)
Carotid artery stenosis	1 (3.3)
Cerebrovascular accident	1 (3.3)
Facial paralysis	1 (3.3)
Hypoglossal nerve paralysis	1 (3.3)
Syncope	1 (3.3)
Transient ischaemic attack	1 (3.3)
Renal and urinary disorders	2 (6.7)
Nephrolithiasis	2 (6.7)
Respiratory, thoracic and mediastinal disorders	1 (3.3)
Pulmonary embolism	1 (3.3)
Surgical and medical procedures	8 (26.7)
Thyroidectomy	2 (6.7)
Aortic valve replacement	1 (3.3)
Carotid artery stent insertion	1 (3.3)
Cataract operation	1 (3.3)
Coronary arterial stent insertion	1 (3.3)

^a Non-Active includes past medical conditions/procedures ended before time of informed consent. Every patient is counted a single time for each applicable specific preferred term. A patient with multiple preferred terms within a system organ class is counted a single time for that system organ class.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-3s 2021-09-22 17:01

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Source data: adsl.xpt, admh.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-3s Non-active medical history (Sub-study safety analysis set)

Final Version

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Surgical and medical procedures (Continued)	
Cyst removal	1 (3.3)
Intervertebral disc operation	1 (3.3)
Meniscus operation	1 (3.3)
Ureteral stent insertion	1 (3.3)
Vascular disorders	2 (6.7)
Deep vein thrombosis	1 (3.3)
Lymphoedema	1 (3.3)

^a Non-Active includes past medical conditions/procedures ended before time of informed consent.
Every patient is counted a single time for each applicable specific preferred term. A patient with multiple preferred terms within a system organ class is counted a single time for that system organ class.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-3s 2021-09-22 17:01

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Source data: adsl.xpt, admh.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-4s Prior cancer-related surgery (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30)
Patients with at least one prostate cancer-related surgery (including biopsies), n (%)	29 (96.7)
Prior number of prostate cancer-related surgeries / biopsies	
n	29
Mean	1.3
SD	0.54
Median	1.0
Min-Max	1-3
Reason for surgery, n (%)	
Diagnostic/biopsy	17 (56.7)
Therapeutic	14 (46.7)
Palliative	2 (6.7)

A patient may be counted in several rows for reason for surgery.

Output ID: T-1-3-4s 2021-09-22 17:02

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-5s Prior cancer-related radiotherapy (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30)
Patients with at least one prostate cancer-related radiotherapy, n (%)	25 (83.3)
Prior number of prostate cancer-related radiotherapies	
n	25
Mean	1.9
SD	1.01
Median	2.0
Min-Max	1-4
Unique sites, n (%)	
Prostate gland	12 (40.0)
Bone	6 (20.0)
Lymph node	5 (16.7)
Hip	4 (13.3)
Vertebral column	4 (13.3)
Other	3 (10.0)
Back	2 (6.7)
Iliac crest	1 (3.3)
Rib	1 (3.3)
Unknown	1 (3.3)

Each unique site will be counted only once for each patient.

Site of radiotherapy are sorted in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Output ID: T-1-3-5s 2021-09-22 17:02

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-6s Prior cancer-related systemic therapy - all therapies (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30)
Prior number of regimens	
n	30
Mean	4.2
SD	1.37
Median	4.0
Min-Max	2-7
Prior number of regimens categories, n (%)	
n	30
1	0
2	3 (10.0)
3	8 (26.7)
>3	19 (63.3)
Prior number of taxane-containing regimens	
n	30
Mean	1.4
SD	0.50
Median	1.0
Min-Max	1-2
Prior number of taxane-containing regimens categories, n (%)	
n	30
1	17 (56.7)
2	13 (43.3)
>2	0
Prior number of NAAD-containing regimens	
n	30
Mean	1.7
SD	0.58
Median	2.0
Min-Max	1-3
Prior number of NAAD-containing regimens categories, n (%)	
n	30
1	10 (33.3)
2	18 (60.0)
>2	2 (6.7)
Reason for therapy, n (%)	
Therapeutic	25 (83.3)
Prophylaxis	6 (20.0)
Maintenance	6 (20.0)
Adjuvant	3 (10.0)
Unknown	3 (10.0)
Number of unique agents	
n	30
Mean	4.7
SD	1.51
Median	5.0
Min-Max	2-7
Type of prior therapy, n (%)	

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)

	Lu-PSMA-617 +BSC/BSoC (N=30)
ANTI-ANDROGENS	24 (80.0)
APALUTAMIDE	1 (3.3)
BICALUTAMIDE	10 (33.3)
ENZALUTAMIDE	22 (73.3)
FLUTAMIDE	2 (6.7)
GLUCOCORTICOIDS	13 (43.3)
PREDNISOLONE	6 (20.0)
PREDNISONE	7 (23.3)
GONADOTROPIN RELEASING HORMONE ANALOGUES	18 (60.0)
BUSERELIN	2 (6.7)
BUSERELIN ACETATE	1 (3.3)
GONADOTROPIN RELEASING HORMONE ANALOGUES	2 (6.7)
LEUPRORELIN	2 (6.7)
LEUPRORELIN ACETATE	10 (33.3)
TRIPTORELIN EMBONATE	1 (3.3)
GONADOTROPIN-RELEASING HORMONES	1 (3.3)
GONADERELIN DIACETATE TETRAHYDRATE	1 (3.3)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	4 (13.3)
DENOSUMAB	4 (13.3)
OTHER HORMONE ANTAGONISTS AND RELATED AGENTS	27 (90.0)
ABIRATERONE	18 (60.0)
ABIRATERONE ACETATE	9 (30.0)
TAXANES	30 (100)
CABAZITAXEL	12 (40.0)
DOCETAXEL	29 (96.7)
PACLITAXEL	1 (3.3)
VARIOUS THERAPEUTIC RADIOPHARMACEUTICALS	1 (3.3)
RADIUM RA 223 DICHLORIDE	1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are presented alphabetically.

A medication/therapy can appear in more than one ATC level.

A patient may be counted in several rows for reasons for therapy.

Taxane includes cabazitaxel, docetaxel or paclitaxel.

NAAD: Novel androgen axis drugs included enzalutamide, abiraterone, or apalutamide.

Coded using WHODrug Global version Mar 2021 B3

Output ID: T-1-3-6s 2021-09-22 17:03

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Source data: adsl.xpt, adpct.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Number of patients with at least one concomitant medication	529 (100)	205 (100)	734 (100)
3-OXOANDROSTEN (4) DERIVATIVES	1 (0.2)	0	1 (0.1)
TESTOSTERONE CIPIONATE	1 (0.2)	0	1 (0.1)
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	4 (0.8)	1 (0.5)	5 (0.7)
AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE	3 (0.6)	0	3 (0.4)
TRANDOLAPRIL;VERAPAMIL HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
AMLODIPINE BESILATE;PERINDOPRIL ARGININE	0	1 (0.5)	1 (0.1)
ACE INHIBITORS AND DIURETICS	9 (1.7)	4 (2.0)	13 (1.8)
HYDROCHLOROTHIAZIDE;LISINOPRIL	5 (0.9)	4 (2.0)	9 (1.2)
INDAPAMIDE;PERINDOPRIL ERBUMINE	2 (0.4)	0	2 (0.3)
BENAZEPRIL;HYDROCHLOROTHIAZIDE	1 (0.2)	0	1 (0.1)
ENALAPRIL MALEATE;HYDROCHLOROTHIAZIDE	1 (0.2)	0	1 (0.1)
ACE INHIBITORS, PLAIN	89 (16.8)	35 (17.1)	124 (16.9)
LISINOPRIL	53 (10.0)	20 (9.8)	73 (9.9)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ACE INHIBITORS, PLAIN (Continued)			
RAMIPRIL	18 (3.4)	4 (2.0)	22 (3.0)
PERINDOPRIL	6 (1.1)	2 (1.0)	8 (1.1)
BENAZEPRIL HYDROCHLORIDE	3 (0.6)	0	3 (0.4)
ENALAPRIL	3 (0.6)	3 (1.5)	6 (0.8)
BENAZEPRIL	2 (0.4)	0	2 (0.3)
ENALAPRIL MALEATE	2 (0.4)	1 (0.5)	3 (0.4)
QUINAPRIL	2 (0.4)	2 (1.0)	4 (0.5)
PERINDOPRIL ERBUMINE	1 (0.2)	2 (1.0)	3 (0.4)
TRANDOLAPRIL	1 (0.2)	0	1 (0.1)
FOSINOPRIL	0	1 (0.5)	1 (0.1)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES			
DICLOFENAC SODIUM	19 (3.6)	10 (4.9)	29 (4.0)
DICLOFENAC	8 (1.5)	3 (1.5)	11 (1.5)
INDOMETACIN	7 (1.3)	3 (1.5)	10 (1.4)
KETOROLAC	2 (0.4)	1 (0.5)	3 (0.4)
	2 (0.4)	0	2 (0.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES (Continued)			
DICLOFENAC;MISOPROSTOL	0	1 (0.5)	1 (0.1)
ETODOLAC	0	1 (0.5)	1 (0.1)
KETOROLAC TROMETHAMINE	0	1 (0.5)	1 (0.1)
ADRENERGIC AND DOPAMINERGIC AGENTS			
MIDODRINE	12 (2.3)	2 (1.0)	14 (1.9)
EPHEDRINE	4 (0.8)	1 (0.5)	5 (0.7)
NOREPINEPHRINE	3 (0.6)	0	3 (0.4)
PHENYLEPHRINE	3 (0.6)	0	3 (0.4)
DROXIDOPA	1 (0.2)	0	1 (0.1)
NOREPINEPHRINE BITARTRATE	1 (0.2)	0	1 (0.1)
PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS			
BUDESONIDE;FORMOTEROL FUMARATE	10 (1.9)	10 (4.9)	20 (2.7)
4 (0.8)	1 (0.5)	5 (0.7)	

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS (Continued)			
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE			
FLUTICASONE;SALMETEROL	3 (0.6)	3 (1.5)	6 (0.8)
BUDESONIDE;FORMOTEROL	2 (0.4)	2 (1.0)	4 (0.5)
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	1 (0.2)	1 (0.5)	2 (0.3)
FORMOTEROL;MOMETASONE	1 (0.2)	0	1 (0.1)
BECLOMETASONE;FORMOTEROL	0	1 (0.5)	1 (0.1)
FLUTICASONE PROPIONATE;SALMETEROL	0	1 (0.5)	1 (0.1)
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS			
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	11 (2.1)	4 (2.0)	15 (2.0)
FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	6 (1.1)	3 (1.5)	9 (1.2)
OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE MONOHYDRATE	2 (0.4)	0	2 (0.3)
FENOTEROL HYDROBROMIDE;IPRATROPIUM BROMIDE	1 (0.2)	0	1 (0.1)
GLYCOPYRRONIUM BROMIDE;INDACATEROL MALEATE	1 (0.2)	0	1 (0.1)
UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	1 (0.2)	0	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS (Continued)			
IPRATROPIUM;SALBUTAMOL	0	1 (0.5)	1 (0.1)
AGENTS FOR DERMATITIS, EXCLUDING CORTICOSTEROIDS	1 (0.2)	0	1 (0.1)
TACROLIMUS	1 (0.2)	0	1 (0.1)
ALDOSTERONE ANTAGONISTS	7 (1.3)	5 (2.4)	12 (1.6)
SPIRONOLACTONE	4 (0.8)	5 (2.4)	9 (1.2)
EPLERENONE	3 (0.6)	0	3 (0.4)
ALPHA AND BETA BLOCKING AGENTS	23 (4.3)	9 (4.4)	32 (4.4)
CARVEDILOL	18 (3.4)	8 (3.9)	26 (3.5)
LABETALOL	5 (0.9)	1 (0.5)	6 (0.8)
LABETALOL HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
ALPHA-ADRENORECEPTOR ANTAGONISTS	77 (14.6)	43 (21.0)	120 (16.3)
TAMSULOSIN	36 (6.8)	15 (7.3)	51 (6.9)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ALPHA-ADRENORECEPTOR ANTAGONISTS (Continued)			
TAMSULOSIN HYDROCHLORIDE	34 (6.4)	16 (7.8)	50 (6.8)
ALFUZOSIN	3 (0.6)	1 (0.5)	4 (0.5)
ALFUZOSIN HYDROCHLORIDE	2 (0.4)	3 (1.5)	5 (0.7)
DOXAZOSIN	2 (0.4)	1 (0.5)	3 (0.4)
SILODOSIN	2 (0.4)	4 (2.0)	6 (0.8)
DOXAZOSIN MESILATE	1 (0.2)	1 (0.5)	2 (0.3)
TERAZOSIN	1 (0.2)	2 (1.0)	3 (0.4)
SOLIFENACIN;TAMSULOSIN	0	1 (0.5)	1 (0.1)
TERAZOSIN HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
URAPIDIL	0	1 (0.5)	1 (0.1)
ALUMINIUM COMPOUNDS	1 (0.2)	0	1 (0.1)
ALUMINIUM HYDROXIDE	1 (0.2)	0	1 (0.1)
AMIDES	41 (7.8)	13 (6.3)	54 (7.4)
LIDOCAINE	34 (6.4)	11 (5.4)	45 (6.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
AMIDES (Continued)			
LIDOCAINE;PRILOCAINE	5 (0.9)	1 (0.5)	6 (0.8)
BUPIVACAINE	2 (0.4)	1 (0.5)	3 (0.4)
ARTICAINE HYDROCHLORIDE;EPINEPHRINE BITARTRATE	1 (0.2)	0	1 (0.1)
BUPIVACAINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
BUPIVACAINE;EPINEPHRINE	1 (0.2)	0	1 (0.1)
EPINEPHRINE;LIDOCAINE	1 (0.2)	1 (0.5)	2 (0.3)
MEPIVACAINE	1 (0.2)	0	1 (0.1)
ROPIVACAINE	0	1 (0.5)	1 (0.1)
AMINO ACIDS			
TRANEXAMIC ACID	2 (0.4)	0	2 (0.3)
AMINO ACIDS AND DERIVATIVES			
LEVOGLUTAMIDE	4 (0.8)	1 (0.5)	5 (0.7)
ACETYLCYSTEINE	3 (0.6)	1 (0.5)	4 (0.5)
LEVOCARNITINE	1 (0.2)	0	1 (0.1)
1 (0.2)	0	1 (0.1)	

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES	2 (0.4)	1 (0.5)	3 (0.4)
ARGININE;BETA-HYDROXY-BETA-METHYLBUTYRATE;LEVOGLUTAMIDE	1 (0.2)	0	1 (0.1)
ISOLEUCINE;LEUCINE;VALINE	1 (0.2)	0	1 (0.1)
ARGININE	0	1 (0.5)	1 (0.1)
AMINOALKYL ETHERS	28 (5.3)	5 (2.4)	33 (4.5)
DIPHENHYDRAMINE HYDROCHLORIDE	17 (3.2)	4 (2.0)	21 (2.9)
DIPHENHYDRAMINE	11 (2.1)	1 (0.5)	12 (1.6)
DIMENHYDRINATE	1 (0.2)	0	1 (0.1)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.2)	3 (1.5)	4 (0.5)
MESALAZINE	1 (0.2)	1 (0.5)	2 (0.3)
BALSALAZIDE DISODIUM DIHYDRATE	0	1 (0.5)	1 (0.1)
SULFASALAZINE	0	1 (0.5)	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANESTHETICS FOR TOPICAL USE	3 (0.6)	2 (1.0)	5 (0.7)
LIDOCAINE;PRILOCAINE	2 (0.4)	2 (1.0)	4 (0.5)
PRAMOCAINE	1 (0.2)	0	1 (0.1)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs) AND CALCIUM CHANNEL BLOCKERS	3 (0.6)	0	3 (0.4)
AMLODIPINE BESILATE;VALSARTAN	2 (0.4)	0	2 (0.3)
AMLODIPINE BESILATE;OLMESARTAN MEDOXOMIL	1 (0.2)	0	1 (0.1)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs) AND DIURETICS	16 (3.0)	3 (1.5)	19 (2.6)
HYDROCHLOROTHIAZIDE;IRBESARTAN	4 (0.8)	0	4 (0.5)
HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM	4 (0.8)	2 (1.0)	6 (0.8)
HYDROCHLOROTHIAZIDE;LOSARTAN	3 (0.6)	0	3 (0.4)
HYDROCHLOROTHIAZIDE;VALSARTAN	3 (0.6)	1 (0.5)	4 (0.5)
CANDESARTAN CILEXETIL;HYDROCHLOROTHIAZIDE	1 (0.2)	0	1 (0.1)
CANDESARTAN;HYDROCHLOROTHIAZIDE	1 (0.2)	0	1 (0.1)
HYDROCHLOROTHIAZIDE;OLMESARTAN	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN	62 (11.7)	22 (10.7)	84 (11.4)
LOSARTAN	29 (5.5)	11 (5.4)	40 (5.4)
CANDESARTAN	11 (2.1)	0	11 (1.5)
LOSARTAN POTASSIUM	8 (1.5)	5 (2.4)	13 (1.8)
VALSARTAN	7 (1.3)	1 (0.5)	8 (1.1)
TELMISARTAN	3 (0.6)	0	3 (0.4)
IRBESARTAN	2 (0.4)	4 (2.0)	6 (0.8)
OLMESARTAN	2 (0.4)	0	2 (0.3)
OLMESARTAN MEDOXOMIL	2 (0.4)	0	2 (0.3)
CANDESARTAN CILEXETIL	0	1 (0.5)	1 (0.1)
ANILIDES	218 (41.2)	95 (46.3)	313 (42.6)
PARACETAMOL	206 (38.9)	91 (44.4)	297 (40.5)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	6 (1.1)	1 (0.5)	7 (1.0)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (0.4)	3 (1.5)	5 (0.7)
ACETYLSALICYLIC ACID;ALUMINIUM HYDROXIDE GEL,	1 (0.2)	0	1 (0.1)
DRIED;CAFFEINE;MAGNESIUM HYDROXIDE;PARACETAMOL			
BUTALBITAL;CAFFEINE;PARACETAMOL	1 (0.2)	1 (0.5)	2 (0.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANILIDES (Continued)			
CHLORPHENAMINE MALEATE;PARACETAMOL	1 (0.2)	0	1 (0.1)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
DIPHENHYDRAMINE;PARACETAMOL	1 (0.2)	0	1 (0.1)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL	0	2 (1.0)	2 (0.3)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
ANTACIDS WITH ANTIFLATULENTS	1 (0.2)	0	1 (0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	1 (0.2)	0	1 (0.1)
ANTACIDS WITH SODIUM BICARBONATE	1 (0.2)	0	1 (0.1)
SODIUM BICARBONATE	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANTI-ANDROGENS			
ENZALUTAMIDE	183 (34.6)	100 (48.8)	283 (38.6)
BICALUTAMIDE	158 (29.9)	89 (43.4)	247 (33.7)
APALUTAMIDE	16 (3.0)	10 (4.9)	26 (3.5)
DAROLUTAMIDE	10 (1.9)	1 (0.5)	11 (1.5)
NILUTAMIDE	2 (0.4)	2 (1.0)	4 (0.5)
	1 (0.2)	0	1 (0.1)
ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS			
AZELASTINE	6 (1.1)	0	6 (0.8)
AZELASTINE HYDROCHLORIDE	5 (0.9)	0	5 (0.7)
	1 (0.2)	0	1 (0.1)
ANTIANDROGENS, PLAIN			
CYPROTERONE	2 (0.4)	2 (1.0)	4 (0.5)
CYPROTERONE ACETATE	2 (0.4)	0	2 (0.3)
	0	2 (1.0)	2 (0.3)
ANTIARRHYTHMICS, CLASS IC			
FLECAINIDE	4 (0.8)	0	4 (0.5)
PROPAFENONE	3 (0.6)	0	3 (0.4)
	1 (0.2)	0	1 (0.1)

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Output ID: T-1-3-7 2021-09-22 17:00

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANTIARRHYTHMICS, CLASS III	4 (0.8)	6 (2.9)	10 (1.4)
AMIODARONE	4 (0.8)	5 (2.4)	9 (1.2)
AMIODARONE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
ANTIBIOTICS	9 (1.7)	4 (2.0)	13 (1.8)
NYSTATIN	7 (1.3)	3 (1.5)	10 (1.4)
CHLORAMPHENICOL	1 (0.2)	0	1 (0.1)
NYSTATIN;TRIAMCINOLONE	1 (0.2)	0	1 (0.1)
AMPHOTERICIN B	0	1 (0.5)	1 (0.1)
ANTICHOLINERGICS	12 (2.3)	5 (2.4)	17 (2.3)
TIOTROPIUM	3 (0.6)	1 (0.5)	4 (0.5)
ATROPINE	2 (0.4)	0	2 (0.3)
IPRATROPIUM	2 (0.4)	0	2 (0.3)
TIOTROPIUM BROMIDE MONOHYDRATE	2 (0.4)	3 (1.5)	5 (0.7)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANTICHOLINERGICS (Continued)			
ACLDINIUM BROMIDE	1 (0.2)	1 (0.5)	2 (0.3)
CYCLOPENTOLATE	1 (0.2)	0	1 (0.1)
CYCLOPENTOLATE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
IPRATROPIUM BROMIDE	1 (0.2)	0	1 (0.1)
UMECLIDINIUM BROMIDE	1 (0.2)	0	1 (0.1)
ANTICHOLINESTERASES			
NEOSTIGMINE	6 (1.1)	0	6 (0.8)
DONEPEZIL	2 (0.4)	0	2 (0.3)
DONEPEZIL HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
DONEPEZIL HYDROCHLORIDE;MEMANTINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
NEOSTIGMINE METILSULFATE	1 (0.2)	0	1 (0.1)
ANTICORTICOSTEROIDS			
KETOCONAZOLE	2 (0.4)	5 (2.4)	7 (1.0)
	2 (0.4)	5 (2.4)	7 (1.0)

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A medication/therapy can appear in more than one ATC level.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANTIDIARRHEAL MICROORGANISMS			
PROBIOTICS NOS	25 (4.7)	9 (4.4)	34 (4.6)
LACTOBACILLUS ACIDOPHILUS	10 (1.9)	4 (2.0)	14 (1.9)
ANTIDIARRHEAL MICROORGANISMS	4 (0.8)	1 (0.5)	5 (0.7)
LACTOBACILLUS NOS	3 (0.6)	0	3 (0.4)
BACILLUS COAGULANS;INULIN	3 (0.6)	0	3 (0.4)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LACTIS;LACTOBACILLUS	1 (0.2)	0	1 (0.1)
ACIDOPHILUS;LACTOBACILLUS BREVIS;LACTOBACILLUS			
BULGARICUS;LACTOBACILLUS CASEI;LACTOBACILLUS			
PARACASEI;LACTOBACILLUS PLANTARUM;LACTOBACILLUS			
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS	1 (0.2)	0	1 (0.1)
ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS			
HELVETICUS;LACTOBACILLUS PLANTARUM;LACTOBACILLUS RHAMNOSUS			
BIFIDOBACTERIUM INFANTIS	1 (0.2)	0	1 (0.1)
LACTOBACILLUS RHAMNOSUS	1 (0.2)	0	1 (0.1)
BACILLUS COAGULANS;CALCIUM CARBONATE	0	1 (0.5)	1 (0.1)
BIFIDOBACTERIUM ANIMALIS;LACTOBACILLUS ACIDOPHILUS	0	1 (0.5)	1 (0.1)
COLOSTRUM	0	1 (0.5)	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANTIDIARRHEAL MICROORGANISMS (Continued)			
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS	0	1 (0.5)	1 (0.1)
ANTIDOTES			
SUGAMMADEX	4 (0.8)	1 (0.5)	5 (0.7)
GLUTATHIONE	2 (0.4)	1 (0.5)	3 (0.4)
NALOXONE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
ANTIFUNGALS FOR SYSTEMIC USE			
TERBINAFINE	2 (0.4)	0	2 (0.3)
TERBINAFINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
ANTIINFECTIVES			
OFLOXACIN	1 (0.2)	1 (0.5)	2 (0.3)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT			
CHLORHEXIDINE GLUCONATE	20 (3.8) 6 (1.1)	3 (1.5) 2 (1.0)	23 (3.1) 8 (1.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANTIIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT (Continued)			
NYSTATIN	5 (0.9)	1 (0.5)	6 (0.8)
CHLORHEXIDINE	4 (0.8)	0	4 (0.5)
AMPHOTERICIN B	3 (0.6)	0	3 (0.4)
POVIDONE-IODINE	2 (0.4)	0	2 (0.3)
ANTIIINFECTIVES FOR TREATMENT OF ACNE			
CLINDAMYCIN	1 (0.2)	0	1 (0.1)
	1 (0.2)	0	1 (0.1)
ANTIINFLAMMATORY AGENTS, NON-STEROIDS			
KETOROLAC	5 (0.9)	0	5 (0.7)
BROMFENAC SODIUM	3 (0.6)	0	3 (0.4)
FLURBIPROFEN SODIUM	1 (0.2)	0	1 (0.1)
INDOMETACIN	1 (0.2)	0	1 (0.1)
KETOROLAC TROMETHAMINE	1 (0.2)	0	1 (0.1)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE			
	14 (2.6)	4 (2.0)	18 (2.5)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE (Continued)			
DICLOFENAC			
DICLOFENAC DIETHYLAMINE	12 (2.3)	3 (1.5)	15 (2.0)
DICLOFENAC SODIUM	1 (0.2)	0	1 (0.1)
NIFLUMIC ACID	1 (0.2)	0	1 (0.1)
NIFLUMIC ACID	0	1 (0.5)	1 (0.1)
ANTINEOVASCULARISATION AGENTS			
RANIBIZUMAB	1 (0.2)	1 (0.5)	2 (0.3)
RANIBIZUMAB	1 (0.2)	1 (0.5)	2 (0.3)
ANTIPROPULSIVES			
LOPERAMIDE HYDROCHLORIDE	48 (9.1)	13 (6.3)	61 (8.3)
LOPERAMIDE	28 (5.3)	7 (3.4)	35 (4.8)
ATROPINE SULFATE;DIPHENOXYLATE HYDROCHLORIDE	16 (3.0)	4 (2.0)	20 (2.7)
ATROPINE;DIPHENOXYLATE	7 (1.3)	1 (0.5)	8 (1.1)
ATROPINE;DIPHENOXYLATE	1 (0.2)	1 (0.5)	2 (0.3)
ANTIVIRALS			
ACICLOVIR	2 (0.4)	0	2 (0.3)
ACICLOVIR	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANTIVIRALS (Continued)			
IMIQUIMOD	1 (0.2)	0	1 (0.1)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS			
EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE	2 (0.4)	2 (1.0)	4 (0.5)
BICTEGRAVIR;EMTRICITABINE;TENOFOVIR	2 (0.4)	0	2 (0.3)
EFAVIRENZ;EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE	0	1 (0.5)	1 (0.1)
ARYLOXYACETIC ACID DERIVATIVES			
ETACRYNIC ACID	0	1 (0.5)	1 (0.1)
ASCORBIC ACID (VITAMIN C), COMBINATIONS			
ASCORBIC ACID;ROSA CANINA	0	1 (0.5)	1 (0.1)
ASCORBIC ACID (VITAMIN C), PLAIN			
ASCORBIC ACID	2 (0.4)	0	2 (0.3)
CALCIUM ASCORBATE	38 (7.2)	13 (6.3)	51 (6.9)
	37 (7.0)	12 (5.9)	49 (6.7)
	1 (0.2)	1 (0.5)	2 (0.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ASCORBIC ACID (VITAMIN C), PLAIN (Continued)			
SODIUM ASCORBATE	1 (0.2)	0	1 (0.1)
AZASPIRODECANEDIONE DERIVATIVES	2 (0.4)	0	2 (0.3)
BUSPIRONE HYDROCHLORIDE	2 (0.4)	0	2 (0.3)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS	1 (0.2)	0	1 (0.1)
HYOSCINE	1 (0.2)	0	1 (0.1)
BELLADONNA ALKALOIDS, TERTIARY AMINES	2 (0.4)	0	2 (0.3)
ATROPINE	1 (0.2)	0	1 (0.1)
ATROPINE SULFATE	1 (0.2)	0	1 (0.1)
BENZIMIDAZOLE DERIVATIVES	0	1 (0.5)	1 (0.1)
FENBENDAZOLE	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
BENZODIAZEPINE DERIVATIVES			
LORAZEPAM	88 (16.6)	33 (16.1)	121 (16.5)
ALPRAZOLAM	43 (8.1)	13 (6.3)	56 (7.6)
DIAZEPAM	24 (4.5)	8 (3.9)	32 (4.4)
OXAZEPAM	9 (1.7)	2 (1.0)	11 (1.5)
CLONAZEPAM	7 (1.3)	1 (0.5)	8 (1.1)
MIDAZOLAM	6 (1.1)	3 (1.5)	9 (1.2)
MIDAZOLAM HYDROCHLORIDE	5 (0.9)	2 (1.0)	7 (1.0)
BENZODIAZEPINE DERIVATIVES	TEMAZEPAM	4 (0.8)	6 (0.8)
BROMAZEPAM	3 (0.6)	3 (1.5)	6 (0.8)
LORMETAZEPAM	1 (0.2)	0	1 (0.1)
NITRAZEPAM	1 (0.2)	2 (1.0)	3 (0.4)
CLORAZEPATE DIPOTASSIUM	1 (0.2)	0	1 (0.1)
PRAZEPAM	0	1 (0.5)	1 (0.1)
0	1 (0.5)	1 (0.1)	
BENZODIAZEPINE RELATED DRUGS	40 (7.6)	12 (5.9)	52 (7.1)
ZOPICLONE	17 (3.2)	7 (3.4)	24 (3.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
BENZODIAZEPINE RELATED DRUGS (Continued)			
ZOLPIDEM	14 (2.6)	1 (0.5)	15 (2.0)
ZOLPIDEM TARTRATE	10 (1.9)	3 (1.5)	13 (1.8)
ESZOPICLONE	0	1 (0.5)	1 (0.1)
BENZOTHIAZEPINE DERIVATIVES			
DILTIAZEM	14 (2.6)	1 (0.5)	15 (2.0)
DILTIAZEM HYDROCHLORIDE	10 (1.9)	1 (0.5)	11 (1.5)
DILTIAZEM HYDROCHLORIDE	4 (0.8)	0	4 (0.5)
BETA BLOCKING AGENTS			
BRIMONIDINE TARTRATE;TIMOLOL MALEATE	12 (2.3)	4 (2.0)	16 (2.2)
TIMOLOL	4 (0.8)	1 (0.5)	5 (0.7)
TIMOLOL MALEATE	4 (0.8)	2 (1.0)	6 (0.8)
DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE	4 (0.8)	0	4 (0.5)
TIMOLOL MALEATE;TRAVOPROST	1 (0.2)	0	1 (0.1)
TIMOLOL;TRAVOPROST	1 (0.2)	0	1 (0.1)
BIMATOPROST;TIMOLOL MALEATE	1 (0.2)	0	1 (0.1)
BIMATOPROST;TIMOLOL MALEATE	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
BETA BLOCKING AGENTS, NON-SELECTIVE	6 (1.1)	2 (1.0)	8 (1.1)
PROPRANOLOL	3 (0.6)	1 (0.5)	4 (0.5)
SOTALOL	2 (0.4)	0	2 (0.3)
PROPRANOLOL HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
NADOLOL	0	1 (0.5)	1 (0.1)
BETA BLOCKING AGENTS, SELECTIVE	96 (18.1)	45 (22.0)	141 (19.2)
METOPROLOL	34 (6.4)	14 (6.8)	48 (6.5)
METOPROLOL SUCCINATE	16 (3.0)	11 (5.4)	27 (3.7)
ATENOLOL	14 (2.6)	5 (2.4)	19 (2.6)
BISOPROLOL	12 (2.3)	8 (3.9)	20 (2.7)
METOPROLOL TARTRATE	10 (1.9)	6 (2.9)	16 (2.2)
NEBIVOLOL HYDROCHLORIDE	6 (1.1)	2 (1.0)	8 (1.1)
BISOPROLOL FUMARATE	4 (0.8)	0	4 (0.5)
NEBIVOLOL	3 (0.6)	1 (0.5)	4 (0.5)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
BETA BLOCKING AGENTS, SELECTIVE (Continued)			
ACEBUTOLOL	1 (0.2)	0	1 (0.1)
ESMOLOL	1 (0.2)	0	1 (0.1)
BETA BLOCKING AGENTS, SELECTIVE, AND THIAZIDES			
BISOPROLOL FUMARATE;HYDROCHLOROTHIAZIDE	3 (0.6)	1 (0.5)	4 (0.5)
HYDROCHLOROTHIAZIDE;NEBIVOLOL HYDROCHLORIDE	3 (0.6)	0	3 (0.4)
HYDROCHLOROTHIAZIDE;NEBIVOLOL HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
BETA-LACTAMASE INHIBITORS			
CLAVULANIC ACID	1 (0.2)	0	1 (0.1)
CLAVULANIC ACID	1 (0.2)	0	1 (0.1)
BETA-LACTAMASE RESISTANT PENICILLINS			
FLUCLOXACILLIN	3 (0.6)	1 (0.5)	4 (0.5)
DICLOXA CILLIN SODIUM MONOHYDRATE	2 (0.4)	0	2 (0.3)
CLOXA CILLIN SODIUM	1 (0.2)	0	1 (0.1)
DICLOXA CILLIN	0	1 (0.5)	1 (0.1)
DICLOXA CILLIN	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
BETA-LACTAMASE SENSITIVE PENICILLINS	1 (0.2)	0	1 (0.1)
BENZYL PENICILLIN	1 (0.2)	0	1 (0.1)
PHENOXYMETHYL PENICILLIN	1 (0.2)	0	1 (0.1)
BIGUANIDES	70 (13.2)	33 (16.1)	103 (14.0)
METFORMIN	60 (11.3)	29 (14.1)	89 (12.1)
METFORMIN HYDROCHLORIDE	11 (2.1)	4 (2.0)	15 (2.0)
BIGUANIDES AND AMIDINES	1 (0.2)	1 (0.5)	2 (0.3)
CHLORHEXIDINE GLUCONATE	1 (0.2)	0	1 (0.1)
CHLORHEXIDINE	0	1 (0.5)	1 (0.1)
BIOFLAVONOIDS	1 (0.2)	1 (0.5)	2 (0.3)
DIOSMIN	1 (0.2)	0	1 (0.1)
ACETYL-L-CARNITINE ARGINATE;ARGININE;DIOSMIN;ENZYME NOS;HERBAL NOS;HESPERIDIN;LEVOCARNITINE PROPIONATE;TOCOTRIENOLS NOS	0	1 (0.5)	1 (0.1)
BISMUTH PREPARATIONS	3 (0.6)	1 (0.5)	4 (0.5)

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
BISMUTH PREPARATIONS (Continued)			
BISMUTH SUBSALICYLATE	3 (0.6)	1 (0.5)	4 (0.5)
BISPHOSPHONATES			
ZOLEDRONIC ACID MONOHYDRATE	45 (8.5)	28 (13.7)	73 (9.9)
ZOLEDRONIC ACID	19 (3.6)	15 (7.3)	34 (4.6)
ALENDRONATE SODIUM	18 (3.4)	8 (3.9)	26 (3.5)
ALENDRONIC ACID	4 (0.8)	4 (2.0)	8 (1.1)
RISEDRONATE SODIUM	2 (0.4)	2 (1.0)	4 (0.5)
RISEDRONATE SODIUM	2 (0.4)	0	2 (0.3)
BISPHOSPHONATES, COMBINATIONS			
CALCIUM CARBONATE;RISEDRONATE SODIUM	1 (0.2)	1 (0.5)	2 (0.3)
ALENDRONATE SODIUM;VITAMIN D NOS	1 (0.2)	0	1 (0.1)
ALENDRONATE SODIUM;VITAMIN D NOS	0	1 (0.5)	1 (0.1)
BLOOD COAGULATION FACTORS			
FACTOR I (FIBRINOGEN);FACTOR VIII (ANTIIAEMOPHILIC FACTOR);FACTOR XIII (FIBRIN STABILISING FACTOR);VON WILLEBRAND FACTOR	1 (0.2)	0	1 (0.1)
FACTOR I (FIBRINOGEN);FACTOR VIII (ANTIIAEMOPHILIC FACTOR);FACTOR XIII (FIBRIN STABILISING FACTOR);VON WILLEBRAND FACTOR	1 (0.2)	0	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS	4 (0.8)	2 (1.0)	6 (0.8)
ALBUMIN HUMAN	4 (0.8)	2 (1.0)	6 (0.8)
BULK-FORMING LAXATIVES	13 (2.5)	1 (0.5)	14 (1.9)
PSYLLIUM HYDROPHILIC MUCILLOID	5 (0.9)	1 (0.5)	6 (0.8)
PLANTAGO PSYLLIUM	3 (0.6)	0	3 (0.4)
PLANTAGO OVATA	2 (0.4)	0	2 (0.3)
PLANTAGO AFRA	1 (0.2)	0	1 (0.1)
POLYCARBOPHIL CALCIUM	1 (0.2)	0	1 (0.1)
STERCULIA URENS GUM	1 (0.2)	0	1 (0.1)
BUTYROPHENONE DERIVATIVES	4 (0.8)	2 (1.0)	6 (0.8)
HALOPERIDOL	4 (0.8)	2 (1.0)	6 (0.8)
<u>CALCINEURIN INHIBITORS</u>	1 (0.2)	0	1 (0.1)

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
CALCINEURIN INHIBITORS (Continued)			
TACROLIMUS	1 (0.2)	0	1 (0.1)
CALCITONIN PREPARATIONS	1 (0.2)	0	1 (0.1)
CALCITONIN, SALMON	1 (0.2)	0	1 (0.1)
CALCIUM	110 (20.8)	59 (28.8)	169 (23.0)
CALCIUM	64 (12.1)	37 (18.0)	101 (13.8)
CALCIUM CARBONATE	41 (7.8)	18 (8.8)	59 (8.0)
CALCIUM CITRATE	8 (1.5)	3 (1.5)	11 (1.5)
CALCIUM ACETATE	1 (0.2)	2 (1.0)	3 (0.4)
CALCIUM GLUCONATE	0	2 (1.0)	2 (0.3)
CALCIUM COMPOUNDS	15 (2.8)	2 (1.0)	17 (2.3)
CALCIUM CARBONATE	15 (2.8)	2 (1.0)	17 (2.3)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	147 (27.8)	60 (29.3)	207 (28.2)

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Output ID: T-1-3-7 2021-09-22 17:00

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS (Continued)			
CALCIUM CARBONATE;COLECALCIFEROL	72 (13.6)	30 (14.6)	102 (13.9)
CALCIUM;VITAMIN D NOS	34 (6.4)	15 (7.3)	49 (6.7)
CALCIUM;COLECALCIFEROL	21 (4.0)	6 (2.9)	27 (3.7)
CALCIUM CARBONATE;VITAMIN D NOS	8 (1.5)	4 (2.0)	12 (1.6)
CALCIUM CITRATE;VITAMIN D NOS	4 (0.8)	1 (0.5)	5 (0.7)
CALCIUM;MAGNESIUM	3 (0.6)	1 (0.5)	4 (0.5)
CALCIUM CITRATE;COLECALCIFEROL	2 (0.4)	2 (1.0)	4 (0.5)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	2 (0.4)	0	2 (0.3)
CALCIUM;MAGNESIUM;ZINC	2 (0.4)	0	2 (0.3)
CALCIUM CARBONATE;CALCIUM GLUCONATE;ERGOCALCIFEROL	1 (0.2)	0	1 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;MAGNESIUM OXIDE;ZINC OXIDE	1 (0.2)	0	1 (0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM	1 (0.2)	0	1 (0.1)
CALCIUM;MAGNESIUM;VITAMIN D NOS;ZINC	1 (0.2)	0	1 (0.1)
CALCIUM CARBONATE;ERGOCALCIFEROL	0	2 (1.0)	2 (0.3)
CALCIUM;MAGNESIUM OXIDE	0	1 (0.5)	1 (0.1)

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Output ID: T-1-3-7 2021-09-22 17:00

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
CAPSAICIN AND SIMILAR AGENTS	2 (0.4)	1 (0.5)	3 (0.4)
CAPSAICIN	1 (0.2)	1 (0.5)	2 (0.3)
CAPSICUM SPP.	1 (0.2)	0	1 (0.1)
CARBAMIC ACID ESTERS	1 (0.2)	2 (1.0)	3 (0.4)
METHOCARBAMOL	1 (0.2)	1 (0.5)	2 (0.3)
METHOCARBAMOL;PARACETAMOL	0	1 (0.5)	1 (0.1)
CARBAMIDE PRODUCTS	1 (0.2)	0	1 (0.1)
UREA	1 (0.2)	0	1 (0.1)
CARBAPENEMS	1 (0.2)	1 (0.5)	2 (0.3)
MEROPENEM	1 (0.2)	0	1 (0.1)
IMIPENEM	0	1 (0.5)	1 (0.1)
CARBOHYDRATES	2 (0.4)	0	2 (0.3)
DEXTRIN	1 (0.2)	0	1 (0.1)
GLUCOSE	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
CARBONIC ANHYDRASE INHIBITORS			
ACETAZOLAMIDE	4 (0.8)	1 (0.5)	5 (0.7)
DORZOLAMIDE	2 (0.4)	0	2 (0.3)
BRIMONIDINE TARTRATE;BRINZOLAMIDE	2 (0.4)	0	2 (0.3)
BRIMONIDINE;BRINZOLAMIDE	1 (0.2)	0	1 (0.1)
BRINZOLAMIDE	1 (0.2)	0	1 (0.1)
	0	1 (0.5)	1 (0.1)
CARIES PROPHYLACTIC AGENTS			
SODIUM FLUORIDE	3 (0.6)	1 (0.5)	4 (0.5)
SODIUM FLUOROPHOSPHATE	1 (0.2)	1 (0.5)	2 (0.3)
XYLITOL	1 (0.2)	0	1 (0.1)
	1 (0.2)	0	1 (0.1)
CENTRALLY ACTING SYMPATHOMIMETICS			
METHYLPHENIDATE HYDROCHLORIDE	12 (2.3)	4 (2.0)	16 (2.2)
	8 (1.5)	2 (1.0)	10 (1.4)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	1 (0.2)	0	1 (0.1)
ATOMOXETINE	1 (0.2)	0	1 (0.1)
METHYLPHENIDATE	1 (0.2)	1 (0.5)	2 (0.3)
MODAFINIL	1 (0.2)	0	1 (0.1)
ATOMOXETINE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
CHOLERA VACCINES	0	1 (0.5)	1 (0.1)
CHOLERA VACCINE INACT WHOLE CELL RCTB ORAL	0	1 (0.5)	1 (0.1)
CHOLINE DERIVATIVES	3 (0.6)	0	3 (0.4)
SUXAMETHONIUM CHLORIDE	3 (0.6)	0	3 (0.4)
COLONY STIMULATING FACTORS	13 (2.5)	3 (1.5)	16 (2.2)
FILGRASTIM	7 (1.3)	0	7 (1.0)
PEGFILGRASTIM	5 (0.9)	3 (1.5)	8 (1.1)
FILGRASTIM SNDZ	2 (0.4)	0	2 (0.3)
LENOGRASTIM	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	3 (0.6)	0	3 (0.4)
CALCIUM CARBONATE;MAGNESIUM CARBONATE	1 (0.2)	0	1 (0.1)
CALCIUM CARBONATE;MAGNESIUM HYDROXIDE	1 (0.2)	0	1 (0.1)
MAGALDRATE	1 (0.2)	0	1 (0.1)
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	2 (0.4)	1 (0.5)	3 (0.4)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	2 (0.4)	0	2 (0.3)
GLIBENCLAMIDE;METFORMIN HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	46 (8.7)	10 (4.9)	56 (7.6)
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	25 (4.7)	4 (2.0)	29 (4.0)
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	13 (2.5)	2 (1.0)	15 (2.0)
AMOXICILLIN;CLAVULANATE POTASSIUM	6 (1.1)	0	6 (0.8)
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	2 (0.4)	0	2 (0.3)
AMOXICILLIN;CLAVULANIC ACID	2 (0.4)	3 (1.5)	5 (0.7)
AMPICILLIN;SULBACTAM	1 (0.2)	1 (0.5)	2 (0.3)
AMPICILLIN SODIUM;SULBACTAM SODIUM	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS			
(Continued)			
PIPERACILLIN;TAZOBACTAM	0	1 (0.5)	1 (0.1)
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES			
SULFAMETHOXAZOLE;TRIMETHOPRIM	22 (4.2) 22 (4.2)	5 (2.4) 5 (2.4)	27 (3.7) 27 (3.7)
COMBINATIONS OF VARIOUS LIPID MODIFYING AGENTS			
EZETIMIBE;SIMVASTATIN	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
COMBINATIONS OF VITAMINS			
COLECALCIFEROL;MENADIONE	5 (0.9) 2 (0.4)	1 (0.5) 0	6 (0.8) 2 (0.3)
COLECALCIFEROL;MENAQUINONE	1 (0.2)	0	1 (0.1)
COMBINATIONS OF VITAMINS			
VITAMIN B NOS	1 (0.2)	0	1 (0.1)
CALCIUM MEFOLINATE;PYRIDOXINE HYDROCHLORIDE;VITAMIN B12 NOS	0	1 (0.5)	1 (0.1)
CONTACT LAXATIVES	70 (13.2)	14 (6.8)	84 (11.4)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
CONTACT LAXATIVES (Continued)			
BISACODYL	22 (4.2)	4 (2.0)	26 (3.5)
SENNOSIDE A+B	22 (4.2)	3 (1.5)	25 (3.4)
SODIUM PICOSULFATE	11 (2.1)	2 (1.0)	13 (1.8)
DOCUSATE;SENN ALEXANDRINA	9 (1.7)	3 (1.5)	12 (1.6)
DOCUSATE SODIUM;SENN ALEXANDRINA	5 (0.9)	0	5 (0.7)
DOCUSATE SODIUM;SENNOSIDE A+B	4 (0.8)	2 (1.0)	6 (0.8)
ALOE FEROX	1 (0.2)	0	1 (0.1)
SENN ALEXANDRINA;SENN SPP.	1 (0.2)	0	1 (0.1)
CORTICOSTEROID DERIVATIVES	0	1 (0.5)	1 (0.1)
CORTICOSTEROID NOS	0	1 (0.5)	1 (0.1)
CORTICOSTEROIDS			
FLUTICASONE PROPIONATE	26 (4.9)	13 (6.3)	39 (5.3)
FLUTICASONE	14 (2.6)	4 (2.0)	18 (2.5)
MOMETASONE	5 (0.9)	7 (3.4)	12 (1.6)
	2 (0.4)	0	2 (0.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
CORTICOSTEROIDS (Continued)			
AZELASTINE;FLUTICASONE	1 (0.2)	0	1 (0.1)
CINCHOCAINE HYDROCHLORIDE;FRAMYCETIN SULFATE;HYDROCORTISONE	1 (0.2)	0	1 (0.1)
DEXAMETHASONE	1 (0.2)	0	1 (0.1)
HYDROCORTISONE ACETATE	1 (0.2)	0	1 (0.1)
TRIAMCINOLONE ACETONIDE	1 (0.2)	0	1 (0.1)
HYDROCORTISONE	0	2 (1.0)	2 (0.3)
MOMETASONE FUROATE	0	1 (0.5)	1 (0.1)
CORTICOSTEROIDS ACTING LOCALLY	1 (0.2)	0	1 (0.1)
BUDESONIDE	1 (0.2)	0	1 (0.1)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION			
DEXAMETHASONE;TOBRAMYCIN	4 (0.8)	1 (0.5)	5 (0.7)
DEXAMETHASONE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	3 (0.6)	0	3 (0.4)
CIPROFLOXACIN HYDROCHLORIDE;DEXAMETHASONE	2 (0.4)	0	2 (0.3)
	0	1 (0.5)	1 (0.1)

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A medication/therapy can appear in more than one ATC level.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)			
TRIAMCINOLONE ACETONIDE	16 (3.0)	7 (3.4)	23 (3.1)
TRIAMCINOLONE	9 (1.7)	1 (0.5)	10 (1.4)
HYDROCORTISONE	6 (1.1)	4 (2.0)	10 (1.4)
DESONIDE	1 (0.2)	1 (0.5)	2 (0.3)
	0	1 (0.5)	1 (0.1)
CORTICOSTEROIDS, PLAIN			
PREDNISOLONE ACETATE	9 (1.7)	1 (0.5)	10 (1.4)
PREDNISOLONE	4 (0.8)	1 (0.5)	5 (0.7)
DEXAMETHASONE SODIUM PHOSPHATE	2 (0.4)	0	2 (0.3)
LOTEPREDNOL ETABONATE	1 (0.2)	0	1 (0.1)
PREDNISONE	1 (0.2)	0	1 (0.1)
PREDNISONE ACETATE	1 (0.2)	0	1 (0.1)
CORTICOSTEROIDS, POTENT (GROUP III)			
FLUOCINONIDE	6 (1.1)	4 (2.0)	10 (1.4)
BETAMETHASONE DIPROPIONATE	3 (0.6)	0	3 (0.4)
DESOXIMETASONE	1 (0.2)	0	1 (0.1)
	1 (0.2)	0	1 (0.1)

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Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
CORTICOSTEROIDS, POTENT (GROUP III) (Continued)			
MOMETASONE FUROATE	1 (0.2)	1 (0.5)	2 (0.3)
BETAMETHASONE	0	1 (0.5)	1 (0.1)
FLUOCINOLONE ACETONIDE	0	1 (0.5)	1 (0.1)
ULOBOETASOL PROPIONATE	0	1 (0.5)	1 (0.1)
CORTICOSTEROIDS, VERY POTENT (GROUP IV)			
CLOBETASOL PROPIONATE	1 (0.2)	4 (2.0)	5 (0.7)
CLOBETASOL	0	2 (1.0)	3 (0.4)
CORTICOSTEROIDS, WEAK (GROUP I)			
HYDROCORTISONE	3 (0.6)	0	3 (0.4)
3 (0.6)	0	3 (0.4)	
COXIBS			
CELECOXIB	11 (2.1)	7 (3.4)	18 (2.5)
ETORICOXIB	10 (1.9)	7 (3.4)	17 (2.3)
	1 (0.2)	0	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
DETOXIFYING AGENTS FOR ANTINEOPLASTIC TREATMENT	3 (0.6)	0	3 (0.4)
CALCIUM FOLINATE	2 (0.4)	0	2 (0.3)
RASBURICASE	1 (0.2)	0	1 (0.1)
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	12 (2.3)	7 (3.4)	19 (2.6)
OLANZAPINE	11 (2.1)	6 (2.9)	17 (2.3)
QUETIAPINE	1 (0.2)	1 (0.5)	2 (0.3)
DIGITALIS GLYCOSIDES	2 (0.4)	1 (0.5)	3 (0.4)
DIGOXIN	2 (0.4)	1 (0.5)	3 (0.4)
DIHYDROPYRIDINE DERIVATIVES	104 (19.7)	38 (18.5)	142 (19.3)
AMLODIPINE	74 (14.0)	25 (12.2)	99 (13.5)
AMLODIPINE BESILATE	20 (3.8)	10 (4.9)	30 (4.1)
FELODIPINE	5 (0.9)	0	5 (0.7)
NICARDIPINE HYDROCHLORIDE	3 (0.6)	1 (0.5)	4 (0.5)
LERCANIDIPINE	2 (0.4)	1 (0.5)	3 (0.4)
NIFEDIPINE	2 (0.4)	0	2 (0.3)

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
DIHYDROPYRIDINE DERIVATIVES (Continued)			
LERCANIDIPINE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS			
SITAGLIPTIN PHOSPHATE	9 (1.7)	2 (1.0)	11 (1.5)
LINAGLIPTIN	6 (1.1)	2 (1.0)	8 (1.1)
SAXAGLIPTIN HYDROCHLORIDE	2 (0.4)	0	2 (0.3)
SAXAGLIPTIN HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
DIPHENYLMETHANE DERIVATIVES			
HYDROXYZINE	1 (0.2)	0	1 (0.1)
DIPHENYLPROPYLAMINE DERIVATIVES			
METHADONE	1 (0.2)	0	1 (0.1)
METHADONE HYDROCHLORIDE	14 (2.6)	3 (1.5)	17 (2.3)
METHADONE HYDROCHLORIDE	13 (2.5)	2 (1.0)	15 (2.0)
METHADONE HYDROCHLORIDE	1 (0.2)	1 (0.5)	2 (0.3)
DIRECT FACTOR XA INHIBITORS			
RIVAROXABAN	63 (11.9)	24 (11.7)	87 (11.9)
RIVAROXABAN	32 (6.0)	10 (4.9)	42 (5.7)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
DIRECT FACTOR XA INHIBITORS (Continued)			
APIXABAN	28 (5.3)	12 (5.9)	40 (5.4)
EDOXABAN	5 (0.9)	1 (0.5)	6 (0.8)
EDOXABAN TOSILATE	1 (0.2)	1 (0.5)	2 (0.3)
DIRECT THROMBIN INHIBITORS			
DABIGATRAN ETEXILATE MESILATE	4 (0.8)	1 (0.5)	5 (0.7)
ARGATROBAN	2 (0.4)	0	2 (0.3)
DABIGATRAN ETEXILATE	1 (0.2)	0	1 (0.1)
DABIGATRAN	1 (0.2)	0	1 (0.1)
	0	1 (0.5)	1 (0.1)
DOPA AND DOPA DERIVATIVES			
CARBIDOPA;LEVODOPA	4 (0.8)	1 (0.5)	5 (0.7)
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	2 (0.4)	0	2 (0.3)
BENSERAZIDE;LEVODOPA	1 (0.2)	1 (0.5)	2 (0.3)
CARBIDOPA	1 (0.2)	0	1 (0.1)
LEVODOPA	1 (0.2)	0	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
DOPAMINE AGONISTS	10 (1.9)	3 (1.5)	13 (1.8)
ROPINIROLE	4 (0.8)	1 (0.5)	5 (0.7)
PRAMIPEXOLE	3 (0.6)	0	3 (0.4)
PRAMIPEXOLE DIHYDROCHLORIDE	1 (0.2)	1 (0.5)	2 (0.3)
ROPINIROLE HYDROCHLORIDE	1 (0.2)	1 (0.5)	2 (0.3)
ROTIGOTINE	1 (0.2)	0	1 (0.1)
DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA	4 (0.8)	2 (1.0)	6 (0.8)
SODIUM POLYSTYRENE SULFONATE	3 (0.6)	0	3 (0.4)
SEVELAMER CARBONATE	1 (0.2)	0	1 (0.1)
CALCIUM ACETATE;MAGNESIUM CARBONATE	0	1 (0.5)	1 (0.1)
SEVELAMER	0	1 (0.5)	1 (0.1)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	40 (7.6)	11 (5.4)	51 (6.9)
OXYBUTYNIN	13 (2.5)	3 (1.5)	16 (2.2)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE (Continued)			
MIRABEGRON	10 (1.9)	2 (1.0)	12 (1.6)
OXYBUTYNIN HYDROCHLORIDE	9 (1.7)	1 (0.5)	10 (1.4)
SOLIFENACIN	5 (0.9)	1 (0.5)	6 (0.8)
SOLIFENACIN SUCCINATE	3 (0.6)	2 (1.0)	5 (0.7)
FESOTERODINE FUMARATE	1 (0.2)	1 (0.5)	2 (0.3)
TOLTERODINE	1 (0.2)	0	1 (0.1)
TROSPiUM CHLORIDE	1 (0.2)	1 (0.5)	2 (0.3)
DARIFENACIN	0	1 (0.5)	1 (0.1)
DRUGS USED IN ERECTILE DYSFUNCTION			
TADALAFIL	12 (2.3)	3 (1.5)	15 (2.0)
SILDENAFIL	5 (0.9)	2 (1.0)	7 (1.0)
SILDENAFIL CITRATE	3 (0.6)	1 (0.5)	4 (0.5)
ALPROSTADIL	3 (0.6)	0	3 (0.4)
ALPROSTADIL;PAPAVERINE;PHENTOLAMINE	1 (0.2)	0	1 (0.1)
VARDENAFIL HYDROCHLORIDE	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
DRUGS USED IN ERECTILE DYSFUNCTION (Continued)			
PAPAVERINE;PHENTOLAMINE	0	1 (0.5)	1 (0.1)
DRUGS USED IN NICOTINE DEPENDENCE			
VARENICLINE TARTRATE	3 (0.6)	1 (0.5)	4 (0.5)
NICOTINE POLACRILEX	2 (0.4)	0	2 (0.3)
NICOTINE	1 (0.2)	0	1 (0.1)
NALOXONE	0	1 (0.5)	1 (0.1)
DRUGS USED IN OPIOID DEPENDENCE			
NALOXONE	3 (0.6)	0	3 (0.4)
ELECTROLYTE SOLUTIONS			
SODIUM CHLORIDE	68 (12.9)	15 (7.3)	83 (11.3)
MAGNESIUM SULFATE	62 (11.7)	11 (5.4)	73 (9.9)
POTASSIUM CHLORIDE	8 (1.5)	0	8 (1.1)
CALCIUM GLUCONATE	7 (1.3)	2 (1.0)	9 (1.2)
SODIUM BICARBONATE	4 (0.8)	2 (1.0)	6 (0.8)
	3 (0.6)	1 (0.5)	4 (0.5)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ELECTROLYTE SOLUTIONS (Continued)			
POTASSIUM PHOSPHATE DIBASIC	2 (0.4)	0	2 (0.3)
SODIUM PHOSPHATE	2 (0.4)	0	2 (0.3)
CALCIUM CHLORIDE	1 (0.2)	0	1 (0.1)
POTASSIUM ACETATE	1 (0.2)	0	1 (0.1)
POTASSIUM	0	1 (0.5)	1 (0.1)
ENEMAS			
BISACODYL	13 (2.5)	4 (2.0)	17 (2.3)
SODIUM CITRATE;SODIUM LAURYL SULFOACETATE	5 (0.9)	0	5 (0.7)
DOCUSATE SODIUM	3 (0.6)	1 (0.5)	4 (0.5)
DOCUSATE;SORBITOL	2 (0.4)	1 (0.5)	3 (0.4)
ENEMAS	1 (0.2)	0	1 (0.1)
GLYCEROL	1 (0.2)	0	1 (0.1)
GLYCEROL;SODIUM CITRATE;SODIUM LAURYL SULFOACETATE	1 (0.2)	0	1 (0.1)
SODIUM PHOSPHATE	1 (0.2)	0	1 (0.1)
BISACODYL;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ENEMAS (Continued)			
SODIUM LAURYL SULFATE;SORBITOL	0	1 (0.5)	1 (0.1)
ENZYME PREPARATIONS			
BROMELAINS;RUTOSIDE;TRYPSIN	4 (0.8)	1 (0.5)	5 (0.7)
CARICA PAPAYA	1 (0.2)	0	1 (0.1)
ENZYME PREPARATIONS			
PANCREATIN	1 (0.2)	0	1 (0.1)
PROTEASE NOS	0	1 (0.5)	1 (0.1)
ENZYMES			
ALTEPLASE	2 (0.4)	0	2 (0.3)
CHYMOTRYPSIN;PAPAIN;SELENIUM;TRYPSIN	1 (0.2)	0	1 (0.1)
ESTROGENS			
ESTRADIOL	12 (2.3)	1 (0.5)	13 (1.8)
DIETHYLSTILBESTROL	10 (1.9)	0	10 (1.4)
	3 (0.6)	1 (0.5)	4 (0.5)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
EXPECTORANTS	7 (1.3)	4 (2.0)	11 (1.5)
GUAIFENESIN	7 (1.3)	4 (2.0)	11 (1.5)
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMBINATIONS CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEIN;VITAMINS NOS	3 (0.6) 3 (0.6)	1 (0.5) 1 (0.5)	4 (0.5) 4 (0.5)
FATTY ACID DERIVATIVES	1 (0.2)	1 (0.5)	2 (0.3)
VALPROATE SODIUM	1 (0.2)	0	1 (0.1)
VALPROIC ACID	0	1 (0.5)	1 (0.1)
FIBRATES	10 (1.9)	2 (1.0)	12 (1.6)
FENOFLIBRATE	9 (1.7)	1 (0.5)	10 (1.4)
GEMFIBROZIL	1 (0.2)	0	1 (0.1)
CHOLINE FENOFLIBRATE	0	1 (0.5)	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
FIRST-GENERATION CEPHALOSPORINS			
CEFALEXIN	14 (2.6)	4 (2.0)	18 (2.5)
CEFAZOLIN	10 (1.9)	4 (2.0)	14 (1.9)
CEFAZOLIN SODIUM	5 (0.9)	0	5 (0.7)
	1 (0.2)	0	1 (0.1)
FLUORIDE			
SODIUM FLUORIDE	1 (0.2)	0	1 (0.1)
	1 (0.2)	0	1 (0.1)
FLUOROQUINOLONES			
CIPROFLOXACIN	56 (10.6)	6 (2.9)	62 (8.4)
LEVOFLOXACIN	30 (5.7)	2 (1.0)	32 (4.4)
CIPROFLOXACIN HYDROCHLORIDE	19 (3.6)	3 (1.5)	22 (3.0)
OFLOXACIN	5 (0.9)	1 (0.5)	6 (0.8)
MOXIFLOXACIN	3 (0.6)	0	3 (0.4)
BESIFLOXACIN HYDROCHLORIDE	2 (0.4)	0	2 (0.3)
MOXIFLOXACIN HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
	1 (0.2)	0	1 (0.1)
FOLIC ACID AND DERIVATIVES	17 (3.2)	13 (6.3)	30 (4.1)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGMT-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
FOLIC ACID AND DERIVATIVES (Continued)			
FOLIC ACID	17 (3.2)	13 (6.3)	30 (4.1)
FOURTH-GENERATION CEPHALOSPORINS			
CEFEPIME	6 (1.1)	0	6 (0.8)
CEFEPIME HYDROCHLORIDE	4 (0.8)	0	4 (0.5)
CEFEPIME HYDROCHLORIDE;GLUCOSE	1 (0.2)	0	1 (0.1)
CEFEPIME HYDROCHLORIDE;GLUCOSE	1 (0.2)	0	1 (0.1)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES			
LIRAGLUTIDE	4 (0.8)	1 (0.5)	5 (0.7)
DULAGLUTIDE	3 (0.6)	1 (0.5)	4 (0.5)
DULAGLUTIDE	1 (0.2)	0	1 (0.1)
GLUCOCORTICOIDS			
PREDNISONE	344 (65.0)	137 (66.8)	481 (65.5)
DEXAMETHASONE	183 (34.6)	79 (38.5)	262 (35.7)
PREDNISOLONE	164 (31.0)	35 (17.1)	199 (27.1)
HYDROCORTISONE	43 (8.1)	24 (11.7)	67 (9.1)
HYDROCORTISONE	12 (2.3)	6 (2.9)	18 (2.5)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
GLUCOCORTICOIDS (Continued)			
METHYLPREDNISOLONE	10 (1.9)	5 (2.4)	15 (2.0)
CORTISONE	4 (0.8)	1 (0.5)	5 (0.7)
FLUTICASONE PROPIONATE	4 (0.8)	0	4 (0.5)
BETAMETHASONE SODIUM PHOSPHATE	3 (0.6)	2 (1.0)	5 (0.7)
FLUTICASONE	3 (0.6)	0	3 (0.4)
TRIAMCINOLONE ACETONIDE	3 (0.6)	1 (0.5)	4 (0.5)
BUDESONIDE	2 (0.4)	0	2 (0.3)
METHYLPREDNISOLONE SODIUM SUCCINATE	2 (0.4)	2 (1.0)	4 (0.5)
TRIAMCINOLONE	2 (0.4)	0	2 (0.3)
CICLESONIDE	1 (0.2)	0	1 (0.1)
DEXAMETHASONE SODIUM SUCCINATE	1 (0.2)	0	1 (0.1)
BECLOMETASONE DIPROPIONATE	0	1 (0.5)	1 (0.1)
DEXAMETHASONE ACETATE	0	1 (0.5)	1 (0.1)
FLUTICASONE FUROATE	0	1 (0.5)	1 (0.1)
METHYLPREDNISOLONE ACETATE	0	1 (0.5)	1 (0.1)
MOMETASONE FUROATE	0	1 (0.5)	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
GLYCOGENOLYTIC HORMONES	2 (0.4)	0	2 (0.3)
GLUCAGON	2 (0.4)	0	2 (0.3)
GLYCOPEPTIDE ANTIBACTERIALS	11 (2.1)	2 (1.0)	13 (1.8)
VANCOMYCIN	10 (1.9)	1 (0.5)	11 (1.5)
VANCOMYCIN HYDROCHLORIDE	1 (0.2)	1 (0.5)	2 (0.3)
GONADOTROPIN RELEASING HORMONE ANALOGUES	468 (88.5)	172 (83.9)	640 (87.2)
LEUPRORELIN ACETATE	309 (58.4)	96 (46.8)	405 (55.2)
LEUPRORELIN	74 (14.0)	33 (16.1)	107 (14.6)
GOSEREWIN ACETATE	34 (6.4)	16 (7.8)	50 (6.8)
GOSEREWIN	20 (3.8)	8 (3.9)	28 (3.8)
TRIPTORELIN ACETATE	19 (3.6)	10 (4.9)	29 (4.0)
TRIPTORELIN EMBONATE	14 (2.6)	7 (3.4)	21 (2.9)
TRIPTORELIN	7 (1.3)	3 (1.5)	10 (1.4)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
GONADOTROPIN RELEASING HORMONE ANALOGUES (Continued)			
BUSERELIN ACETATE	0	1 (0.5)	1 (0.1)
H2-RECEPTOR ANTAGONISTS			
FAMOTIDINE	36 (6.8)	14 (6.8)	50 (6.8)
RANITIDINE	16 (3.0)	7 (3.4)	23 (3.1)
RANITIDINE HYDROCHLORIDE	15 (2.8)	5 (2.4)	20 (2.7)
CIMETIDINE	4 (0.8)	2 (1.0)	6 (0.8)
	2 (0.4)	0	2 (0.3)
HEPARIN GROUP			
ENOXAPARIN SODIUM	41 (7.8)	14 (6.8)	55 (7.5)
HEPARIN	10 (1.9)	5 (2.4)	15 (2.0)
ENOXAPARIN	9 (1.7)	2 (1.0)	11 (1.5)
TINZAPARIN SODIUM	8 (1.5)	3 (1.5)	11 (1.5)
DALTEPARIN	7 (1.3)	3 (1.5)	10 (1.4)
DALTEPARIN SODIUM	5 (0.9)	0	5 (0.7)
TINZAPARIN	3 (0.6)	3 (1.5)	6 (0.8)
	3 (0.6)	0	3 (0.4)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
HEPARIN GROUP (Continued)			
NADROPARIN CALCIUM	2 (0.4)	0	2 (0.3)
HEPARIN;SODIUM CHLORIDE	1 (0.2)	0	1 (0.1)
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	2 (0.4)	0	2 (0.3)
BOSWELLIA SERRATA	2 (0.4)	0	2 (0.3)
HERBAL DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	1 (0.2)	0	1 (0.1)
SERENOA REPENS EXTRACT	1 (0.2)	0	1 (0.1)
HERBAL IMMUNOMODULATORS	1 (0.2)	0	1 (0.1)
LENTINUS EDODES MYCELIUM	1 (0.2)	0	1 (0.1)
HERBAL URINARY ANTISEPTICS AND ANTIINFECTIVES	1 (0.2)	0	1 (0.1)
VACCINIUM MACROCARPON	1 (0.2)	0	1 (0.1)
HIGH-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
HIGH-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS (Continued)			
AMILORIDE HYDROCHLORIDE;FUROSEMIDE	1 (0.2)	0	1 (0.1)
HMG COA REDUCTASE INHIBITORS			
ATORVASTATIN	199 (37.6)	78 (38.0)	277 (37.7)
SIMVASTATIN	80 (15.1)	28 (13.7)	108 (14.7)
ATORVASTATIN CALCIUM	41 (7.8)	11 (5.4)	52 (7.1)
ROUVASTATIN	28 (5.3)	16 (7.8)	44 (6.0)
ROUVASTATIN CALCIUM	20 (3.8)	6 (2.9)	26 (3.5)
PRAVASTATIN	16 (3.0)	9 (4.4)	25 (3.4)
PRAVASTATIN SODIUM	9 (1.7)	7 (3.4)	16 (2.2)
LOVASTATIN	4 (0.8)	2 (1.0)	6 (0.8)
PITAVASTATIN CALCIUM	2 (0.4)	2 (1.0)	4 (0.5)
HYDANTOIN DERIVATIVES	2 (0.4)	0	2 (0.3)
PHENYTOIN	1 (0.2)	1 (0.5)	2 (0.3)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
HYDRAZINOPHTHALAZINE DERIVATIVES	14 (2.6)	2 (1.0)	16 (2.2)
HYDRALAZINE	12 (2.3)	2 (1.0)	14 (1.9)
HYDRALAZINE HYDROCHLORIDE	2 (0.4)	0	2 (0.3)
IMIDAZOLE AND TRIAZOLE DERIVATIVES	6 (1.1)	2 (1.0)	8 (1.1)
KETOCONAZOLE	3 (0.6)	0	3 (0.4)
CLOTRIMAZOLE	2 (0.4)	1 (0.5)	3 (0.4)
ECONAZOLE	1 (0.2)	0	1 (0.1)
BETAMETHASONE;CLOTRIMAZOLE	0	1 (0.5)	1 (0.1)
IMIDAZOLE DERIVATIVES	5 (0.9)	2 (1.0)	7 (1.0)
METRONIDAZOLE	5 (0.9)	2 (1.0)	7 (1.0)
IMIDAZOLINE RECEPTOR AGONISTS	4 (0.8)	3 (1.5)	7 (1.0)
CLONIDINE	2 (0.4)	3 (1.5)	5 (0.7)
CLONIDINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
MOXONIDINE	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
INDIFFERENT PREPARATIONS	0	1 (0.5)	1 (0.1)
UREA HYDROGEN PEROXIDE	0	1 (0.5)	1 (0.1)
INFLUENZA VACCINES	13 (2.5)	1 (0.5)	14 (1.9)
INFLUENZA VACCINE	10 (1.9)	1 (0.5)	11 (1.5)
INFLUENZA VACCINE INACT SPLIT 3V	2 (0.4)	0	2 (0.3)
INFLUENZA VACCINE INACT SPLIT 4V	1 (0.2)	0	1 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	30 (5.7)	3 (1.5)	33 (4.5)
INSULIN ASPART	13 (2.5)	1 (0.5)	14 (1.9)
INSULIN LISPRO	11 (2.1)	1 (0.5)	12 (1.6)
INSULIN	9 (1.7)	0	9 (1.2)
INSULIN GLULISINE	1 (0.2)	1 (0.5)	2 (0.3)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	3 (0.6)	0	3 (0.4)
INSULIN	1 (0.2)	0	1 (0.1)
INSULIN ASPART;INSULIN ASPART PROTAMINE (CRYSTALLINE)	1 (0.2)	0	1 (0.1)

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ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING (Continued)			
INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE			
	1 (0.2)	0	1 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING			
INSULIN HUMAN INJECTION, ISOPHANE	2 (0.4)	0	2 (0.3)
ISOPHANE INSULIN	1 (0.2)	0	1 (0.1)
ISOPHANE INSULIN	1 (0.2)	0	1 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING			
INSULIN GLARGINE	20 (3.8)	3 (1.5)	23 (3.1)
INSULIN DEGLUDEC	11 (2.1)	2 (1.0)	13 (1.8)
INSULIN DETEMIR	6 (1.1)	0	6 (0.8)
INSULIN DETEMIR	4 (0.8)	1 (0.5)	5 (0.7)
INTEGRASE INHIBITORS			
DOLUTEGRAVIR SODIUM	2 (0.4)	0	2 (0.3)
RALTEGRAVIR POTASSIUM	1 (0.2)	0	1 (0.1)
RALTEGRAVIR POTASSIUM	1 (0.2)	0	1 (0.1)
INTERMEDIATE-ACTING SULFONAMIDES			
	1 (0.2)	1 (0.5)	2 (0.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
INTERMEDIATE-ACTING SULFONAMIDES (Continued)			
SULFAMETHOXAZOLE	1 (0.2)	1 (0.5)	2 (0.3)
IRON BIVALENT, ORAL PREPARATIONS			
FERROUS SULFATE	29 (5.5)	21 (10.2)	50 (6.8)
IRON	19 (3.6)	12 (5.9)	31 (4.2)
ASCORBIC ACID;IRON	8 (1.5)	6 (2.9)	14 (1.9)
FERROUS GLUCONATE	1 (0.2)	0	1 (0.1)
FERROUS FUMARATE	1 (0.2)	1 (0.5)	2 (0.3)
IRON POLYSACCHARIDE COMPLEX	0	1 (0.5)	1 (0.1)
IRON IN COMBINATION WITH FOLIC ACID	0	0	1 (0.1)
FOLIC ACID;IRON PIDOLATE	1 (0.2)	0	1 (0.1)
IRON IN OTHER COMBINATIONS			
FERROUS GLUCONATE;HERBAL NOS;VITAMINS NOS	1 (0.2)	0	1 (0.1)
	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
IRON TRIVALENT, ORAL PREPARATIONS	2 (0.4)	0	2 (0.3)
IRON	2 (0.4)	0	2 (0.3)
IRON, PARENTERAL PREPARATIONS	2 (0.4)	4 (2.0)	6 (0.8)
FERRIC CARBOXYMALTPOSE	1 (0.2)	2 (1.0)	3 (0.4)
IRON	1 (0.2)	0	1 (0.1)
SACCHARATED IRON OXIDE	0	2 (1.0)	2 (0.3)
LEUKOTRIENE RECEPTOR ANTAGONISTS	7 (1.3)	9 (4.4)	16 (2.2)
MONTELUKAST	5 (0.9)	6 (2.9)	11 (1.5)
MONTELUKAST SODIUM	2 (0.4)	3 (1.5)	5 (0.7)
LINCOBAMIDES	6 (1.1)	2 (1.0)	8 (1.1)
CLINDAMYCIN	4 (0.8)	0	4 (0.5)
CLINDAMYCIN HYDROCHLORIDE	3 (0.6)	2 (1.0)	5 (0.7)
LIVER THERAPY	1 (0.2)	0	1 (0.1)
LACTULOSE	1 (0.2)	0	1 (0.1)

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	2 (0.4)	2 (1.0)	4 (0.5)
AMILORIDE HYDROCHLORIDE;HYDROCHLOROTHIAZIDE	1 (0.2)	0	1 (0.1)
HYDROCHLOROTHIAZIDE;TRIAMTERENE	1 (0.2)	2 (1.0)	3 (0.4)
MACROLIDES	9 (1.7)	8 (3.9)	17 (2.3)
AZITHROMYCIN	7 (1.3)	7 (3.4)	14 (1.9)
ERYTHROMYCIN	2 (0.4)	1 (0.5)	3 (0.4)
MAGNESIUM	30 (5.7)	15 (7.3)	45 (6.1)
MAGNESIUM	14 (2.6)	8 (3.9)	22 (3.0)
MAGNESIUM OXIDE	8 (1.5)	4 (2.0)	12 (1.6)
MAGNESIUM GLYCEROPHOSPHATE	2 (0.4)	0	2 (0.3)
MAGNESIUM HYDROXIDE	2 (0.4)	0	2 (0.3)
COLECALCIFEROL;MAGNESIUM OXIDE;VITAMIN B1 NOS	1 (0.2)	0	1 (0.1)
MAGNESIUM CITRATE	1 (0.2)	1 (0.5)	2 (0.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
MAGNESIUM (Continued)			
MAGNESIUM GLYCINATE	1 (0.2)	0	1 (0.1)
MAGNESIUM LACTATE;PYRIDOXINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
MAGNESIUM PIDOLATE	1 (0.2)	0	1 (0.1)
MAGNESIUM SULFATE	1 (0.2)	0	1 (0.1)
MAGNESIUM LACTATE	0	1 (0.5)	1 (0.1)
MAGNESIUM;PYRIDOXINE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
MAGNESIUM COMPOUNDS	0	1 (0.5)	1 (0.1)
MAGNESIUM OXIDE	0	1 (0.5)	1 (0.1)
MEDICAL GASES	6 (1.1)	2 (1.0)	8 (1.1)
OXYGEN	6 (1.1)	2 (1.0)	8 (1.1)
MELATONIN RECEPTOR AGONISTS	27 (5.1)	4 (2.0)	31 (4.2)
MELATONIN	27 (5.1)	4 (2.0)	31 (4.2)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
MINERALOCORTICOIDS	3 (0.6)	2 (1.0)	5 (0.7)
FLUDROCORTISONE	2 (0.4)	2 (1.0)	4 (0.5)
FLUDROCORTISONE ACETATE	1 (0.2)	0	1 (0.1)
MONOAMINE OXIDASE B INHIBITORS	0	1 (0.5)	1 (0.1)
RASAGILINE MESYLATE	0	1 (0.5)	1 (0.1)
MONOCLONAL ANTIBODIES	0	1 (0.5)	1 (0.1)
PEMBROLIZUMAB	0	1 (0.5)	1 (0.1)
MORPHINAN DERIVATIVES	1 (0.2)	0	1 (0.1)
LEVORPHANOL	1 (0.2)	0	1 (0.1)
MUCOLYTICS	1 (0.2)	0	1 (0.1)
ACETYLCYSTEINE	1 (0.2)	0	1 (0.1)
MULTIVITAMINS WITH MINERALS	17 (3.2)	7 (3.4)	24 (3.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ASCORBIC ACID;CALCIUM;MINERALS NOS;RETINOL;TOCOPHERYL ACETATE;VITAMIN B NOS;VITAMINS NOS;ZINC MINERALS NOS;VITAMINS NOS	11 (2.1) 2 (0.4)	1 (0.5) 3 (1.5)	12 (1.6) 5 (0.7)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;ERGOCALCIFEROL;IRON;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	1 (0.2)	0	1 (0.1)
ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL	1 (0.2)	0	1 (0.1)
ASCORBIC ACID;CALCIUM;CHROMIUM;FOLIC ACID;MAGNESIUM;PANTOTHENIC ACID;PYRIDOXINE HYDROCHLORIDE;RETINOL;VITAMIN B12 NOS;VITAMIN D NOS;VITAMIN E NOS BIOTIN;CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;POTASSIUM;PROTEINS NOS;SODIUM;VITAMINS NOS	1 (0.2)	2 (1.0)	3 (0.4)
ASCORBIC ACID;CALCIUM CARBONATE;CYANOCOBALAMIN;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL PALMITATE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHEROL	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
MULTIVITAMINS, OTHER COMBINATIONS	1 (0.2)	2 (1.0)	3 (0.4)
MULTIVITAMINS, OTHER COMBINATIONS	1 (0.2)	0	1 (0.1)
ASCORBIC	0	1 (0.5)	1 (0.1)
ACID;BETACAROTENE;BIOTIN;CALCIUM;CHLORIDE;CHROMIUM;COPPER;FOLIC ACID;IODINE;LYCOPENE;MAGNESIUM;MANGANESE;MOLYBDENUM;NICKEL;NIC OTINIC ACID;PANTOTHENIC ACID;PHOSPHORUS;POTASSIUM;PYRIDOXINE MINERALS NOS;VITAMINS NOS	0	1 (0.5)	1 (0.1)
MULTIVITAMINS, PLAIN	77 (14.6)	30 (14.6)	107 (14.6)
VITAMINS NOS	77 (14.6)	30 (14.6)	107 (14.6)
NATURAL OPIUM ALKALOIDS	181 (34.2)	77 (37.6)	258 (35.1)
OXYCODONE	66 (12.5)	21 (10.2)	87 (11.9)
OXYCODONE HYDROCHLORIDE	62 (11.7)	25 (12.2)	87 (11.9)
MORPHINE	39 (7.4)	19 (9.3)	58 (7.9)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
NATURAL OPIUM ALKALOIDS (Continued)			
HYDROMORPHONE	24 (4.5)	7 (3.4)	31 (4.2)
MORPHINE SULFATE	23 (4.3)	17 (8.3)	40 (5.4)
HYDROMORPHONE HYDROCHLORIDE	22 (4.2)	6 (2.9)	28 (3.8)
HYDROCODONE	9 (1.7)	5 (2.4)	14 (1.9)
MORPHINE SULFATE PENTAHYDRATE	4 (0.8)	3 (1.5)	7 (1.0)
CODEINE	1 (0.2)	1 (0.5)	2 (0.3)
NALOXONE HYDROCHLORIDE;OXYCODONE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
OXYMORPHONE	1 (0.2)	0	1 (0.1)
MORPHINE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
NEURAMINIDASE INHIBITORS			
OSELTAMIVIR PHOSPHATE	2 (0.4)	0	2 (0.3)
NICOTINIC ACID AND DERIVATIVES			
NICOTINIC ACID	1 (0.2)	2 (1.0)	3 (0.4)
	1 (0.2)	2 (1.0)	3 (0.4)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
NITROFURAN DERIVATIVES	17 (3.2)	1 (0.5)	18 (2.5)
NITROFURANTOIN	17 (3.2)	1 (0.5)	18 (2.5)
NITROGEN MUSTARD ANALOGUES	0	1 (0.5)	1 (0.1)
CYCLOPHOSPHAMIDE	0	1 (0.5)	1 (0.1)
NITROIMIDAZOLE DERIVATIVES	0	1 (0.5)	1 (0.1)
CLOTrimazole	0	1 (0.5)	1 (0.1)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	11 (2.1)	3 (1.5)	14 (1.9)
NORTRIPTYLINE	4 (0.8)	1 (0.5)	5 (0.7)
CLOMIPRAMINE HYDROCHLORIDE	3 (0.6)	0	3 (0.4)
AMITRIPTYLINE	2 (0.4)	0	2 (0.3)
NORTRIPTYLINE HYDROCHLORIDE	2 (0.4)	1 (0.5)	3 (0.4)
AMITRIPTYLINE HYDROCHLORIDE	1 (0.2)	1 (0.5)	2 (0.3)
IMIPRAMINE	1 (0.2)	0	1 (0.1)
NOT CODED	161 (30.4)	28 (13.7)	189 (25.7)

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ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
NOT CODED (Continued)			
SENNA ALEXANDRINA	35 (6.6)	5 (2.4)	40 (5.4)
SODIUM BICARBONATE	35 (6.6)	2 (1.0)	37 (5.0)
CURCUMA LONGA ROOT	18 (3.4)	1 (0.5)	19 (2.6)
CANNABIS SATIVA	12 (2.3)	3 (1.5)	15 (2.0)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	12 (2.3)	2 (1.0)	14 (1.9)
MEGESTROL	11 (2.1)	3 (1.5)	14 (1.9)
MEGESTROL ACETATE	10 (1.9)	0	10 (1.4)
NUTRIENTS NOS	6 (1.1)	2 (1.0)	8 (1.1)
CURCUMIN	4 (0.8)	0	4 (0.5)
PANAX GINSENG	4 (0.8)	0	4 (0.5)
ALL OTHER THERAPEUTIC PRODUCTS	3 (0.6)	1 (0.5)	4 (0.5)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE	3 (0.6)	0	3 (0.4)
HEXAhydrate;POTASSIUM CHLORIDE;POTASSIUM PHOSPHATE			
DIBASIC;POTASSIUM PHOSPHATE MONOBASIC;SODIUM CHLORIDE			
DIETARY SUPPLEMENT	3 (0.6)	1 (0.5)	4 (0.5)
KRILL OIL	3 (0.6)	1 (0.5)	4 (0.5)

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ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
NOT CODED (Continued)			
PUNICA GRANATUM	3 (0.6)	1 (0.5)	4 (0.5)
SILYBUM MARIANUM	3 (0.6)	0	3 (0.4)
AMINO ACIDS NOS;ELECTROLYTES NOS	2 (0.4)	0	2 (0.3)
BERBERIS VULGARIS ROOT;CAMELLIA SINENSIS LEAF EXTRACT;COPTIS CHINENSIS ROOT;CURCUMA LONGA RHIZOME;ORIGANUM VULGARE LEAF;REYNOUTRIA JAPONICA ROOT WITH RHIZOME;ROSMARINUS OFFICINALIS LEAF;SCUTELLARIA BRASSICA OLERACEA;CAMELLIA SINENSIS;CURCUMA LONGA;PUNICA GRANATUM	2 (0.4)	0	2 (0.3)
CAMELLIA SINENSIS	2 (0.4)	0	2 (0.3)
CANNABIS SATIVA OIL	2 (0.4)	0	2 (0.3)
CINNAMOMUM VERUM BARK	2 (0.4)	0	2 (0.3)
CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN	2 (0.4)	0	2 (0.3)
LINUM USITATISSIMUM OIL	2 (0.4)	1 (0.5)	3 (0.4)
LINUM USITATISSIMUM SEED OIL	2 (0.4)	1 (0.5)	3 (0.4)
LYCOPENE	2 (0.4)	0	2 (0.3)
OTHER MINERAL SUPPLEMENTS	2 (0.4)	0	2 (0.3)

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ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
NOT CODED (Continued)			
OTHER NUTRIENTS	2 (0.4)	1 (0.5)	3 (0.4)
RESVERATROL	2 (0.4)	1 (0.5)	3 (0.4)
TRAMETES VERSICOLOR	2 (0.4)	0	2 (0.3)
VACCINIUM MACROCARPON FRUIT	2 (0.4)	0	2 (0.3)
ACORUS CALAMUS;BACOPA MONNIERI;CELASTRUS PANICULATUS;CENTELLA ASIATICA;EVOLVULUS ALSINOIDES;FOENICULUM VULGARE;GLYCYYRRHIZA GLABRA;MYRISTICA FRAGRANS;TERMINALIA ARJUNA;WITHANIA SOMNIFERA ALISMA ORIENTALE RHIZOME;CORNUS OFFICINALIS FRUIT;DIOSCOREA POLYSTACHYA RHIZOME;PAEONIA X SUFFruticosa ROOT BARK;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA PROCESSED ROOT TUBER	1 (0.2)	0	1 (0.1)
ALLIUM SATIVUM	1 (0.2)	0	1 (0.1)
ALOE VERA	1 (0.2)	0	1 (0.1)
ALOE VERA JUICE	1 (0.2)	0	1 (0.1)
ATROPA BELLADONNA DRY EXTRACT;PAPAVER SOMNIFERUM LATEX	1 (0.2)	0	1 (0.1)
AYURVEDIC PREPARATION NOS	1 (0.2)	0	1 (0.1)

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ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
BOSWELLIA SERRATA RESIN;CAMELLIA SINENSIS LEAF;CARUM CARVI SEED;CURCUMIN;MENTHA X PÍPERITA LEAF;PUNICA GRANATUM FRUIT;RESVERATROL;VITIS VINIFERA SEED;ZINGIBER OFFICINALE ROOT	1 (0.2)	0	1 (0.1)
BRASSICA OLERACEA EXTRACT	1 (0.2)	0	1 (0.1)
BROAD SPECTRUM ANTIBIOTICS	1 (0.2)	0	1 (0.1)
CAMPHOR;EUCALYPTUS GLOBULUS OIL;MENTHOL	1 (0.2)	0	1 (0.1)
CAPSICUM SPP.	1 (0.2)	0	1 (0.1)
CARBOHYDRATES NOS;LIPIDS NOS;MINERALS NOS;PROTEINS NOS	1 (0.2)	0	1 (0.1)
CARICA PAPAYA	1 (0.2)	0	1 (0.1)
CIMICIFUGA RACEMOSA	1 (0.2)	1 (0.5)	2 (0.3)
COUGH AND COLD PREPARATIONS	1 (0.2)	0	1 (0.1)
CURCUMA LONGA	1 (0.2)	0	1 (0.1)
CURCUMA LONGA RHIZOME	1 (0.2)	1 (0.5)	2 (0.3)
CYPROHEPTADINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
DIURETICS	1 (0.2)	0	1 (0.1)
ERIODICTYON CALIFORNICUM	1 (0.2)	0	1 (0.1)
INONOTUS OBliquus	1 (0.2)	0	1 (0.1)
MENTHOL	1 (0.2)	0	1 (0.1)
MONASCUS PURPUREUS	1 (0.2)	0	1 (0.1)

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
NOT CODED (Continued)			
MUCIN	1 (0.2)	0	1 (0.1)
OCIMUM BASILICUM	1 (0.2)	0	1 (0.1)
OENOOTHERA BIENNIS OIL	1 (0.2)	1 (0.5)	2 (0.3)
ORIGANUM MINUTIFLORUM OIL	1 (0.2)	0	1 (0.1)
OTHER COLD PREPARATIONS	1 (0.2)	0	1 (0.1)
PLANTAGO AFRA	1 (0.2)	0	1 (0.1)
PLANTAGO OVATA	1 (0.2)	0	1 (0.1)
PLANTAGO PSYLLIUM	1 (0.2)	1 (0.5)	2 (0.3)
PLANTAGO SPP. POWDER	1 (0.2)	0	1 (0.1)
PROTEIN SUPPLEMENTS	1 (0.2)	0	1 (0.1)
SAMBUCUS NIGRA FLOWER	1 (0.2)	0	1 (0.1)
SENNIA ALEXANDRINA GLYCOSIDE EXTRACT	1 (0.2)	0	1 (0.1)
SPIRULINA SPP.	1 (0.2)	0	1 (0.1)
STERCULIA URENS GUM	1 (0.2)	0	1 (0.1)
TRITICUM AESTIVUM	1 (0.2)	0	1 (0.1)
TRITICUM AESTIVUM GERM OIL	1 (0.2)	0	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
NOT CODED (Continued)			
UNCARIA TOMENTOSA	1 (0.2)	0	1 (0.1)
VACCINIUM MACROCARPON	1 (0.2)	0	1 (0.1)
VALERIANA OFFICINALIS ROOT	1 (0.2)	0	1 (0.1)
ALLICIN;HYSSOPUS OFFICINALIS;PETROSELINUM CRISPUM;TRAMETES VERSICOLOR	0	1 (0.5)	1 (0.1)
ANNONA MURICATA	0	1 (0.5)	1 (0.1)
BETULA spp.;CARUM CARVI;OX BILE;POTENTILLA ANSERINA;RHAMNUS FRANGULA;RHEUM PALMATUM;SENNNA ALEXANDRINA;TARAXACUM OFFICINALE	0	1 (0.5)	1 (0.1)
CALCIUM ALGINATE	0	1 (0.5)	1 (0.1)
EMOLLIENTS AND PROTECTIVES	0	1 (0.5)	1 (0.1)
HELIANTHUS ANNUUS	0	1 (0.5)	1 (0.1)
ISOSORBIDE	0	1 (0.5)	1 (0.1)
ORIGANUM VULGARE	0	1 (0.5)	1 (0.1)
PLANTAGO OVATA FIBRE	0	1 (0.5)	1 (0.1)
SALVIA HISPANICA	0	1 (0.5)	1 (0.1)
ZINGIBER OFFICINALE ROOT	0	1 (0.5)	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	15 (2.8)	3 (1.5)	18 (2.5)
VALACICLOVIR HYDROCHLORIDE	7 (1.3)	1 (0.5)	8 (1.1)
ACICLOVIR	5 (0.9)	2 (1.0)	7 (1.0)
VALACICLOVIR	2 (0.4)	0	2 (0.3)
FAMCICLOVIR	1 (0.2)	0	1 (0.1)
OPIOID ANESTHETICS	7 (1.3)	2 (1.0)	9 (1.2)
FENTANYL	7 (1.3)	2 (1.0)	9 (1.2)
SUFENTANIL	1 (0.2)	0	1 (0.1)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	100 (18.9)	42 (20.5)	142 (19.3)
HYDROCODONE BITARTRATE;PARACETAMOL	31 (5.9)	14 (6.8)	45 (6.1)
HYDROCODONE;PARACETAMOL	30 (5.7)	10 (4.9)	40 (5.4)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	21 (4.0)	8 (3.9)	29 (4.0)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS (Continued)			
CODEINE PHOSPHATE;PARACETAMOL	11 (2.1)	4 (2.0)	15 (2.0)
CODEINE;PARACETAMOL	8 (1.5)	1 (0.5)	9 (1.2)
OXYCODONE HYDROCHLORIDE;OXYCODONE	5 (0.9)	2 (1.0)	7 (1.0)
TEREPHTHALATE;PARACETAMOL			
PAPAVER SOMNIFERUM;PARACETAMOL	2 (0.4)	2 (1.0)	4 (0.5)
PARACETAMOL;TRAMADOL HYDROCHLORIDE	2 (0.4)	3 (1.5)	5 (0.7)
DIHYDROCODEINE;PARACETAMOL	1 (0.2)	0	1 (0.1)
CAFFEINE;PAPAVER SOMNIFERUM LATEX;PARACETAMOL	0	1 (0.5)	1 (0.1)
CODEINE PHOSPHATE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	1 (0.5)	1 (0.1)
OXYCODONE;PARACETAMOL	0	1 (0.5)	1 (0.1)
OPIUM ALKALOIDS AND DERIVATIVES	2 (0.4)	5 (2.4)	7 (1.0)
CODEINE;PROMETHAZINE	1 (0.2)	0	1 (0.1)
DEXTROMETHORPHAN HYDROBROMIDE;PROMETHAZINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE	0	1 (0.5)	1 (0.1)
CODEINE	0	1 (0.5)	1 (0.1)
CODEINE CAMSILATE	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OPIUM ALKALOIDS AND DERIVATIVES (Continued)			
DEXTROMETHORPHAN	0	1 (0.5)	1 (0.1)
HYDROCODONE BITARTRATE	0	1 (0.5)	1 (0.1)
OPIUM DERIVATIVES AND EXPECTORANTS			
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	6 (1.1) 5 (0.9)	1 (0.5) 1 (0.5)	7 (1.0) 6 (0.8)
CODEINE PHOSPHATE;GUAIFENESIN	1 (0.2)	0	1 (0.1)
DEXTROMETHORPHAN;GUAIFENESIN	1 (0.2)	0	1 (0.1)
ORGANIC NITRATES			
GLYCERYL TRINITRATE	16 (3.0) 12 (2.3)	6 (2.9) 5 (2.4)	22 (3.0) 17 (2.3)
ISOSORBIDE MONONITRATE	6 (1.1)	1 (0.5)	7 (1.0)
ISOSORBIDE DINITRATE	0	1 (0.5)	1 (0.1)
ORIPAVINE DERIVATIVES			
BUPRENORPHINE	2 (0.4) 2 (0.4)	0 0	2 (0.3) 2 (0.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OSMOTICALLY ACTING LAXATIVES			
MACROGOL 3350	120 (22.7)	48 (23.4)	168 (22.9)
MACROGOL	52 (9.8)	20 (9.8)	72 (9.8)
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM	34 (6.4)	14 (6.8)	48 (6.5)
CHLORIDE	24 (4.5)	9 (4.4)	33 (4.5)
LACTULOSE	8 (1.5)	4 (2.0)	12 (1.6)
MAGNESIUM HYDROXIDE	4 (0.8)	0	4 (0.5)
MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM	3 (0.6)	0	3 (0.4)
CHLORIDE			
MAGNESIUM CITRATE	3 (0.6)	4 (2.0)	7 (1.0)
MACROGOL 4000	2 (0.4)	3 (1.5)	5 (0.7)
MAGNESIUM OXIDE	1 (0.2)	0	1 (0.1)
SORBITOL	1 (0.2)	1 (0.5)	2 (0.3)
OTHER AGENTS FOR LOCAL ORAL TREATMENT			
GLUCOSE OXIDASE;LACTOFERRIN;LACTOPEROXIDASE;LYSOZYME	24 (4.5)	1 (0.5)	25 (3.4)
MAGIC MOUTHWASH	8 (1.5)	0	8 (1.1)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	7 (1.3)	1 (0.5)	8 (1.1)
BENZYDAMINE HYDROCHLORIDE	3 (0.6)	0	3 (0.4)
	2 (0.4)	0	2 (0.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER AGENTS FOR LOCAL ORAL TREATMENT (Continued)			
CARMELLOSE SODIUM;SORBINICATE	1 (0.2)	0	1 (0.1)
CINEOLE;MENTHOL;METHYL SALICYLATE;THYMOL	1 (0.2)	0	1 (0.1)
CINEOLE;MENTHOL;PINUS SPP. OIL;THYMOL	1 (0.2)	0	1 (0.1)
GLUCOSE OXIDASE;LACTOFERRIN;LACTOPEROXIDASE;LYSOZYME;SODIUM	1 (0.2)	0	1 (0.1)
FLUOROPHOSPHATE			
LIDOCAINE	1 (0.2)	0	1 (0.1)
OTHER AMINOGLYCOSIDES	4 (0.8)	0	4 (0.5)
GENTAMICIN	3 (0.6)	0	3 (0.4)
TOBRAMYCIN	1 (0.2)	0	1 (0.1)
OTHER ANALGESICS AND ANTI PYRETICS	112 (21.2)	48 (23.4)	160 (21.8)
GABAPENTIN	62 (11.7)	18 (8.8)	80 (10.9)
PREGABALIN	24 (4.5)	21 (10.2)	45 (6.1)
CANNABIDIOL	15 (2.8)	4 (2.0)	19 (2.6)
DULOXETINE	9 (1.7)	0	9 (1.2)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANALGESICS AND ANTIPYRETICS (Continued)			
DULOXETINE HYDROCHLORIDE	4 (0.8)	2 (1.0)	6 (0.8)
NEFOPAM HYDROCHLORIDE	3 (0.6)	1 (0.5)	4 (0.5)
AMITRIPTYLINE	2 (0.4)	3 (1.5)	5 (0.7)
AMITRIPTYLINE HYDROCHLORIDE	2 (0.4)	1 (0.5)	3 (0.4)
CANNABIDIOL;DRONABINOL	1 (0.2)	0	1 (0.1)
NEFOPAM	1 (0.2)	0	1 (0.1)
OTHER ANALGESICS AND ANTIPYRETICS	1 (0.2)	0	1 (0.1)
CARBAMAZEPINE	0	1 (0.5)	1 (0.1)
CLONIXIN LYSINATE	0	1 (0.5)	1 (0.1)
OTHER ANTI-DEMENTIA DRUGS			
APOAEQUORIN	1 (0.2)	0	1 (0.1)
OTHER ANTI-PARATHYROID AGENTS			
CINACALCET	1 (0.2)	0	1 (0.1)
1 (0.2)	0	1 (0.1)	

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANTIALLERGICS	2 (0.4)	1 (0.5)	3 (0.4)
AMINOACRIDINE HYDROCHLORIDE;GRAMICIDIN	1 (0.2)	0	1 (0.1)
AZELASTINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
KETOTIFEN	0	1 (0.5)	1 (0.1)
OTHER ANTIANEMIC PREPARATIONS	15 (2.8)	4 (2.0)	19 (2.6)
EPOETIN ALFA	6 (1.1)	3 (1.5)	9 (1.2)
DARBEPOETIN ALFA	5 (0.9)	1 (0.5)	6 (0.8)
EPOETIN ZETA	2 (0.4)	1 (0.5)	3 (0.4)
EPOETIN ALFA EPBX	1 (0.2)	0	1 (0.1)
ROXADUSTAT	1 (0.2)	0	1 (0.1)
OTHER ANTIBACTERIALS	6 (1.1)	2 (1.0)	8 (1.1)
DAPTOMYCIN	1 (0.2)	0	1 (0.1)
FOSFOMYCIN TROMETAMOL	1 (0.2)	0	1 (0.1)
HYOSCYAMINE SULFATE;METHENAMINE;METHYLTHIONINIUM CHLORIDE;PHENYL SALICYLATE;SODIUM PHOSPHATE MONOBASIC (DIHYDRATE)	1 (0.2)	0	1 (0.1)
LINEZOLID	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANTIBACTERIALS (Continued)			
METHENAMINE	1 (0.2)	0	1 (0.1)
OTHER ANTIBACTERIALS	1 (0.2)	1 (0.5)	2 (0.3)
HYOSCYAMINE SULFATE;METHENAMINE;METHYLTHIONINIUM CHLORIDE;PHENYL SALICYLATE;SODIUM PHOSPHATE MONOBASIC	0	1 (0.5)	1 (0.1)
OTHER ANTIBIOTICS FOR TOPICAL USE			
MUPIROCIN	8 (1.5)	2 (1.0)	10 (1.4)
BACITRACIN ZINC;POLYMYXIN B SULFATE	4 (0.8)	1 (0.5)	5 (0.7)
BACITRACIN ZINC;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	2 (0.4)	0	2 (0.3)
FUSIDATE SODIUM	1 (0.2)	0	1 (0.1)
FUSIDIC ACID	1 (0.2)	0	1 (0.1)
BACITRACIN	0	1 (0.5)	1 (0.1)
OTHER ANTIDEPRESSANTS			
MIRTAZAPINE	47 (8.9)	18 (8.8)	65 (8.9)
VENLAFAKLINE	13 (2.5)	7 (3.4)	20 (2.7)
	12 (2.3)	3 (1.5)	15 (2.0)

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ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANTIDEPRESSANTS (Continued)			
TRAZODONE	10 (1.9)	4 (2.0)	14 (1.9)
VENLAFAXINE HYDROCHLORIDE	5 (0.9)	0	5 (0.7)
BUPROPION HYDROCHLORIDE	3 (0.6)	1 (0.5)	4 (0.5)
DULOXETINE	2 (0.4)	1 (0.5)	3 (0.4)
TRAZODONE HYDROCHLORIDE	2 (0.4)	1 (0.5)	3 (0.4)
BUPROPION	1 (0.2)	2 (1.0)	3 (0.4)
MIANSERIN HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
VILAZODONE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
OTHER ANTIDIARRHEALS			
ACACIA SPP.;GALACTOSE;GLUCOSE;HERBAL NOS;LACTOSE;TRANS-GALACTOOLIGOSACCHARIDE	2 (0.4) 1 (0.2)	0 0	2 (0.3) 1 (0.1)
RACECADOTRIL	1 (0.2)	0	1 (0.1)
OTHER ANTIEMETICS			
PROCHLORPERAZINE	90 (17.0) 47 (8.9)	18 (8.8) 8 (3.9)	108 (14.7) 55 (7.5)

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANTIEMETICS (Continued)			
PROCHLORPERAZINE EDISYLATE	16 (3.0)	5 (2.4)	21 (2.9)
DRONABINOL	9 (1.7)	2 (1.0)	11 (1.5)
PROMETHAZINE	9 (1.7)	3 (1.5)	12 (1.6)
HYOSCINE	4 (0.8)	0	4 (0.5)
METOPIMAZINE	3 (0.6)	0	3 (0.4)
DIMENHYDRINATE	2 (0.4)	2 (1.0)	4 (0.5)
PROCHLORPERAZINE MALEATE	2 (0.4)	0	2 (0.3)
PROMETHAZINE HYDROCHLORIDE	2 (0.4)	0	2 (0.3)
MECLOZINE	1 (0.2)	1 (0.5)	2 (0.3)
NABILONE	1 (0.2)	0	1 (0.1)
TRIMETHOBENZAMIDE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
OTHER ANTIEPILEPTICS			
LEVETIRACETAM	8 (1.5)	4 (2.0)	12 (1.6)
LAMOTRIGINE	7 (1.3)	4 (2.0)	11 (1.5)
	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANTIFUNGALS FOR TOPICAL USE	2 (0.4)	0	2 (0.3)
TERBINAFINE HYDROCHLORIDE	2 (0.4)	0	2 (0.3)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	23 (4.3)	11 (5.4)	34 (4.6)
LORATADINE	14 (2.6)	9 (4.4)	23 (3.1)
FEXOFENADINE	4 (0.8)	0	4 (0.5)
DESLORATADINE	3 (0.6)	0	3 (0.4)
FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHENDRINE HYDROCHLORIDE	2 (0.4)	0	2 (0.3)
FEXOFENADINE HYDROCHLORIDE	0	2 (1.0)	2 (0.3)
OTHER ANTIINFECTIVES	0	1 (0.5)	1 (0.1)
BORIC ACID;SODIUM BORATE	0	1 (0.5)	1 (0.1)
OTHER ANTIINFLAMMATORY AND ANTRHEUMATIC AGENTS, NON-STEROIDS	31 (5.9)	4 (2.0)	35 (4.8)
CHONDROITIN;GLUCOSAMINE	10 (1.9)	1 (0.5)	11 (1.5)
GLUCOSAMINE	10 (1.9)	1 (0.5)	11 (1.5)
GLUCOSAMINE SULFATE	3 (0.6)	0	3 (0.4)
OTHER ANTIINFLAMMATORY AND ANTRHEUMATIC AGENTS, NON-STEROIDS	2 (0.4)	0	2 (0.3)

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANTIINFLAMMATORY AND ANTRHEUMATIC AGENTS, NON-STEROIDS (Continued)			
BOSWELLIA SERRATA;CURCUMA LONGA;DL-PHENYLALANINE;NATTOKINASE			
CHONDROITIN SULFATE SODIUM;GLUCOSAMINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
CHONDROITIN SULFATE;GLUCOSAMINE	1 (0.2)	0	1 (0.1)
COLLAGEN	1 (0.2)	0	1 (0.1)
GLUCOSAMINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
METHYLSULFONYLMETHANE	1 (0.2)	0	1 (0.1)
SULFASALAZINE	1 (0.2)	0	1 (0.1)
MORNIFLUMATE	0	1 (0.5)	1 (0.1)
NABUMETONE	0	1 (0.5)	1 (0.1)
OTHER ANTIMIGRAINE PREPARATIONS			
AMITRIPTYLINE	3 (0.6)	3 (1.5)	6 (0.8)
TOPIRAMATE	1 (0.2)	0	1 (0.1)
VENLAFAXINE	1 (0.2)	0	1 (0.1)
AMITRIPTYLINE HYDROCHLORIDE	0	2 (1.0)	2 (0.3)
METOPROLOL	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANTIMYCOTICS FOR SYSTEMIC USE MICAFUNGIN	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
OTHER ANTINEOPLASTIC AGENTS ANAGRELIDE ESTRAMUSTINE PHOSPHATE SODIUM MONOHYDRATE	0 0 0	3 (1.5) 1 (0.5) 2 (1.0)	3 (0.4) 1 (0.1) 2 (0.3)
OTHER ANTIPSORIATICS FOR TOPICAL USE BETAMETHASONE DIPROPIONATE;CALCIPOTRIOL MONOHYDRATE BETAMETHASONE;CALCIPOTRIOL CALCIPOTRIOL	1 (0.2) 1 (0.2) 0 0	3 (1.5) 0 1 (0.5) 2 (1.0)	4 (0.5) 1 (0.1) 1 (0.1) 2 (0.3)
OTHER ANTISSYCHOTICS ARIPIPRAZOLE	2 (0.4) 2 (0.4)	0 0	2 (0.3) 2 (0.3)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANXIOLYTICS	5 (0.9)	2 (1.0)	7 (1.0)
DULOXETINE	1 (0.2)	2 (1.0)	3 (0.4)
DULOXETINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
ESCITALOPRAM	1 (0.2)	0	1 (0.1)
ESCITALOPRAM OXALATE	1 (0.2)	0	1 (0.1)
ETIFOXINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
SERTRALINE	1 (0.2)	0	1 (0.1)
OTHER BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	4 (0.8)	0	4 (0.5)
REPAGLINIDE	4 (0.8)	0	4 (0.5)
OTHER BLOOD PRODUCTS	90 (17.0)	13 (6.3)	103 (14.0)
BLOOD CELLS, PACKED HUMAN	40 (7.6)	5 (2.4)	45 (6.1)
RED BLOOD CELLS	38 (7.2)	8 (3.9)	46 (6.3)
BLOOD, WHOLE	11 (2.1)	2 (1.0)	13 (1.8)
PLATELETS	11 (2.1)	0	11 (1.5)
RED BLOOD CELLS, CONCENTRATED	6 (1.1)	0	6 (0.8)
PLATELETS, CONCENTRATED	3 (0.6)	0	3 (0.4)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER BLOOD PRODUCTS (Continued)			
PLASMA	1 (0.2)	0	1 (0.1)
OTHER CARDIAC PREPARATIONS			
UBIDECARENONE	14 (2.6)	2 (1.0)	16 (2.2)
RANOLAZINE	11 (2.1)	2 (1.0)	13 (1.8)
ADENOSINE	2 (0.4)	0	2 (0.3)
ADENOSINE	1 (0.2)	0	1 (0.1)
OTHER CENTRALLY ACTING AGENTS			
CYCLOBENZAPRINE	27 (5.1)	9 (4.4)	36 (4.9)
CYCLOBENZAPRINE HYDROCHLORIDE	11 (2.1)	3 (1.5)	14 (1.9)
BACLOFEN	8 (1.5)	3 (1.5)	11 (1.5)
DIAZEPAM	4 (0.8)	1 (0.5)	5 (0.7)
TIZANIDINE	2 (0.4)	1 (0.5)	3 (0.4)
TIZANIDINE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
OTHER CHEMOTHERAPEUTICS	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER CHEMOTHERAPEUTICS (Continued)			
INGENOL MEBUTATE	0	1 (0.5)	1 (0.1)
OTHER CICATRIZANTS	1 (0.2)	1 (0.5)	2 (0.3)
LYSINE	1 (0.2)	0	1 (0.1)
CADEXOMER IODINE	0	1 (0.5)	1 (0.1)
OTHER COMBINATIONS OF NUTRIENTS	9 (1.7)	2 (1.0)	11 (1.5)
OTHER COMBINATIONS OF NUTRIENTS	5 (0.9)	0	5 (0.7)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1 (0.2)	1 (0.5)	2 (0.3)
CREATINE	1 (0.2)	0	1 (0.1)
FATTY ACIDS NOS	1 (0.2)	0	1 (0.1)
FISH OIL	1 (0.2)	1 (0.5)	2 (0.3)
OTHER COUGH SUPPRESSANTS	6 (1.1)	2 (1.0)	8 (1.1)
BENZONATATE	6 (1.1)	2 (1.0)	8 (1.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER CYTOTOXIC ANTIBIOTICS CLARITHROMYCIN	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
OTHER DERMATOLOGICALS OTHER DERMATOLOGICALS	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION DENOSUMAB	184 (34.8) 184 (34.8)	80 (39.0) 80 (39.0)	264 (36.0) 264 (36.0)
OTHER DRUGS FOR CONSTIPATION LUBIPROSTONE GLYCEROL LINACLOTIDE	6 (1.1) 4 (0.8) 1 (0.2) 1 (0.2)	4 (2.0) 1 (0.5) 1 (0.5) 2 (1.0)	10 (1.4) 5 (0.7) 2 (0.3) 3 (0.4)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM HYALURONATE SODIUM ASCORBIC ACID;BOSWELLIA SERRATA;CHONDROITIN;GLUCOSAMINE;MANGANESE;METHYLSULFONYLMETH ANE	1 (0.2) 1 (0.2) 0	1 (0.5) 0 1 (0.5)	2 (0.3) 1 (0.1) 1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

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OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	9 (1.7)	2 (1.0)	11 (1.5)
PHLOROGLUCINOL	5 (0.9)	0	5 (0.7)
SIMETICONE	4 (0.8)	2 (1.0)	6 (0.8)
OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	1 (0.2)	0	1 (0.1)
OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	1 (0.2)	0	1 (0.1)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	8 (1.5)	2 (1.0)	10 (1.4)
SUCRALFATE	4 (0.8)	0	4 (0.5)
CALCIUM CARBONATE;SODIUM ALGINATE;SODIUM BICARBONATE	3 (0.6)	1 (0.5)	4 (0.5)
ALGINIC ACID	1 (0.2)	0	1 (0.1)
SODIUM ALGINATE	0	1 (0.5)	1 (0.1)
<u>OTHER DRUGS USED IN BENIGN PROSTATIC HYPERPLASIA</u>	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

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OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY (Continued)			
LYCOPENE	1 (0.2)	0	1 (0.1)
OTHER EMOLLIENTS AND PROTECTIVES			
OTHER EMOLLIENTS AND PROTECTIVES	10 (1.9)	3 (1.5)	13 (1.8)
CETOMACROGOL;PARAFFIN, LIQUID;PROPYLENE GLYCOL;WHITE SOFT	3 (0.6)	0	3 (0.4)
PARAFFIN	2 (0.4)	0	2 (0.3)
AMMONIUM LACTATE	1 (0.2)	1 (0.5)	2 (0.3)
CAMPHOR;MENTHOL	1 (0.2)	0	1 (0.1)
GLYCEROL;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (0.2)	1 (0.5)	2 (0.3)
MAGNESIUM STEARATE	1 (0.2)	0	1 (0.1)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	1 (0.2)	0	1 (0.1)
GLYCEROL	0	1 (0.5)	1 (0.1)
OTHER GENERAL ANESTHETICS			
PROPOFOL	8 (1.5)	1 (0.5)	9 (1.2)
KETAMINE	5 (0.9)	1 (0.5)	6 (0.8)
	4 (0.8)	0	4 (0.5)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER GYNECOLOGICALS	1 (0.2)	0	1 (0.1)
SOYA ISOFLAVONES	1 (0.2)	0	1 (0.1)
OTHER HORMONE ANTAGONISTS AND RELATED AGENTS	149 (28.2)	77 (37.6)	226 (30.8)
ABIRATERONE ACETATE	88 (16.6)	50 (24.4)	138 (18.8)
ABIRATERONE	49 (9.3)	23 (11.2)	72 (9.8)
DEGARELIX ACETATE	12 (2.3)	1 (0.5)	13 (1.8)
DEGARELIX	6 (1.1)	5 (2.4)	11 (1.5)
OTHER HYPNOTICS AND SEDATIVES	7 (1.3)	1 (0.5)	8 (1.1)
DIPHENHYDRAMINE HYDROCHLORIDE	2 (0.4)	0	2 (0.3)
DIPHENHYDRAMINE HYDROCHLORIDE;IBUPROFEN	2 (0.4)	0	2 (0.3)
DEXMEDETOMIDINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
DOXYLAMINE	1 (0.2)	0	1 (0.1)
OTHER HYPNOTICS AND SEDATIVES	1 (0.2)	0	1 (0.1)

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Concomitant medications are all medications starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGMT-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER HYPNOTICS AND SEDATIVES (Continued)			
PROPIOMAZINE MALEATE	0	1 (0.5)	1 (0.1)
OTHER IMMUNOSUPPRESSANTS			
HYDROXYCHLOROQUINE SULFATE	0	1 (0.5)	1 (0.1)
HYDROXYCHLOROQUINE SULFATE	0	1 (0.5)	1 (0.1)
OTHER INTESTINAL ADSORBENTS			
DIOSMECTITE	3 (0.6)	1 (0.5)	4 (0.5)
GELATIN TANNATE	2 (0.4)	1 (0.5)	3 (0.4)
GELATIN TANNATE	1 (0.2)	0	1 (0.1)
OTHER LIPID MODIFYING AGENTS			
FISH OIL	46 (8.7)	14 (6.8)	60 (8.2)
EZETIMIBE	24 (4.5)	11 (5.4)	35 (4.8)
OMEGA-3 FATTY ACIDS	12 (2.3)	1 (0.5)	13 (1.8)
CANNABIS SATIVA OIL;OMEGA-3 FATTY ACIDS	6 (1.1)	0	6 (0.8)
EVOLOCUMAB	1 (0.2)	0	1 (0.1)
FISH OIL;OMEGA-3 FATTY ACIDS	1 (0.2)	1 (0.5)	2 (0.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER LIPID MODIFYING AGENTS (Continued)			
OMEGA 9 FATTY ACIDS;OMEGA-3 FATTY ACIDS;OMEGA-6 FATTY ACIDS	1 (0.2)	0	1 (0.1)
OMEGA-3-ACID ETHYL ESTER	1 (0.2)	0	1 (0.1)
DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID	0	1 (0.5)	1 (0.1)
OTHER LOCAL ANESTHETICS			
ANESTHETICS, LOCAL	1 (0.2)	0	1 (0.1)
OTHER MINERAL PRODUCTS			
BORON CITRATE;CALCIUM CITRATE;COLECALCIFEROL;MAGNESIUM OXIDE;PHYTOMENADIONE;STRONTIUM CITRATE	21 (4.0) 6 (1.1)	2 (1.0) 0	23 (3.1) 6 (0.8)
POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	4 (0.8)	2 (1.0)	6 (0.8)
OTHER MINERAL PRODUCTS	3 (0.6)	0	3 (0.4)
POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE	3 (0.6)	0	3 (0.4)
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	2 (0.4)	0	2 (0.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER MINERAL PRODUCTS (Continued)			
CALCIUM PHOSPHATE MONOBASIC;MAGNESIUM.	1 (0.2)	0	1 (0.1)
GLYCEROPHOSPHATE;PHOSPHORIC ACID;SODIUM PHOSPHATE DIBASIC			
SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	1 (0.2)	0	1 (0.1)
STRONTIUM	1 (0.2)	0	1 (0.1)
OTHER NASAL PREPARATIONS			
SODIUM CHLORIDE	12 (2.3)	3 (1.5)	15 (2.0)
MUPIROCIN	5 (0.9)	1 (0.5)	6 (0.8)
IPRATROPIUM BROMIDE	3 (0.6)	0	3 (0.4)
CAMPHOR;EUCALYPTUS GLOBULUS OIL;MENTHOL;OXYMETAZOLINE HYDROCHLORIDE	2 (0.4)	2 (1.0)	4 (0.5)
OTHER NASAL PREPARATIONS	1 (0.2)	0	1 (0.1)
OTHER NERVOUS SYSTEM DRUGS	2 (0.4)	1 (0.5)	3 (0.4)

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGMlt-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ACETYL CARNITINE; ATRACTYLODES LANCEA RHIZOME; CURCUMA LONGA RHIZOME; CYANOCOBALAMIN; FOLIC ACID; PHELLODENDRON AMURENSE BARK; PHOSPHATIDYL CHOLINE; PYRIDOXINE HYDROCHLORIDE; SCUTELLARIA BAICALENSIS GABAPENTIN	1 (0.2)	0	1 (0.1)
OTHER NON-THERAPEUTIC AUXILIARY PRODUCTS SORBITAN SESQUIOLEATE	1 (0.2) 1 (0.2)	1 (0.5) 0	2 (0.3) 1 (0.1)
OTHER OPHTHALMOLOGICALS CARMELLOSE SODIUM ARTIFICIAL TEARS [UMBRELLA TERM] CARMELLOSE DEXTRAN 70; HYPROMELLOSE HYPROMELLOSE ASCORBIC ACID; BETACAROTENE; CUPRIC OXIDE; TOCOPHERYL ACETATE; ZINC OXIDE ASCORBIC ACID; COPPER CITRATE; TOCOPHERYL ACETATE; XANTOFYL; ZEAXANTHIN; ZINC OXIDE ASCORBIC ACID; TOCOPHERYL ACETATE; XANTOFYL; ZEAXANTHIN; ZINC	27 (5.1) 4 (0.8) 3 (0.6) 3 (0.6) 3 (0.6) 3 (0.6) 2 (0.4) 2 (0.4)	4 (2.0) 0 0 1 (0.5) 1 (0.5) 0 1 (0.5)	31 (4.2) 4 (0.5) 3 (0.4) 4 (0.5) 4 (0.5) 3 (0.4) 3 (0.4) 2 (0.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER OPHTHALMOLOGICALS (Continued)			
CICLOSPORIN	2 (0.4)	0	2 (0.3)
CARBOMER	1 (0.2)	0	1 (0.1)
DEXTRAN	1 (0.2)	0	1 (0.1)
MACROGOL 400	1 (0.2)	0	1 (0.1)
MACROGOL 400;PROPYLENE GLYCOL	1 (0.2)	1 (0.5)	2 (0.3)
POLYVINY ALCOHOL	1 (0.2)	1 (0.5)	2 (0.3)
POLYVINY ALCOHOL;POVIDONE	1 (0.2)	0	1 (0.1)
PROPYLENE GLYCOL	1 (0.2)	0	1 (0.1)
SEA WATER	1 (0.2)	0	1 (0.1)
SODIUM CHLORIDE	1 (0.2)	0	1 (0.1)
XANTOFYL	1 (0.2)	0	1 (0.1)
RETINOL	0	1 (0.5)	1 (0.1)
OTHER OPIOIDS	59 (11.2)	21 (10.2)	80 (10.9)
TRAMADOL	55 (10.4)	16 (7.8)	71 (9.7)
TRAMADOL HYDROCHLORIDE	5 (0.9)	5 (2.4)	10 (1.4)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER OPIOIDS (Continued) TAPENTADOL	1 (0.2)	0	1 (0.1)
OTHER PLAIN VITAMIN PREPARATIONS TOCOPHEROL	21 (4.0) 11 (2.1)	8 (3.9) 4 (2.0)	29 (4.0) 15 (2.0)
PYRIDOXINE HYDROCHLORIDE	5 (0.9)	3 (1.5)	8 (1.1)
BIOTIN	3 (0.6)	1 (0.5)	4 (0.5)
NICOTINAMIDE RIBOSIDE	1 (0.2)	0	1 (0.1)
PYRIDOXINE	1 (0.2)	0	1 (0.1)
VITAMIN E NOS	1 (0.2)	0	1 (0.1)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS OTHER PSYCHOSTIMULANTS AND NOOTROPICS	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
OTHER QUATERNARY AMMONIUM COMPOUNDS ROCURONIUM	4 (0.8) 3 (0.6)	1 (0.5) 0	5 (0.7) 3 (0.4)
ROCURONIUM BROMIDE	1 (0.2)	1 (0.5)	2 (0.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER SYSTEMIC HEMOSTATICS	1 (0.2)	0	1 (0.1)
DESMOPRESSIN ACETATE	1 (0.2)	0	1 (0.1)
OTHER THERAPEUTIC PRODUCTS	0	1 (0.5)	1 (0.1)
NADH	0	1 (0.5)	1 (0.1)
PYRROLOQUINOLINE QUINONE	0	1 (0.5)	1 (0.1)
OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	2 (0.4)	1 (0.5)	3 (0.4)
MENTHOL	2 (0.4)	1 (0.5)	3 (0.4)
OTHER UROLOGICALS	7 (1.3)	2 (1.0)	9 (1.2)
PHENAZOPYRIDINE HYDROCHLORIDE	5 (0.9)	0	5 (0.7)
PENTOSAN POLYSULFATE SODIUM	2 (0.4)	0	2 (0.3)
PENTOSAN POLYSULFATE	0	1 (0.5)	1 (0.1)
PHENAZOPYRIDINE	0	1 (0.5)	1 (0.1)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TFL\\PGMT-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER VASODILATORS USED IN CARDIAC DISEASES	0	1 (0.5)	1 (0.1)
NICORANDIL	0	1 (0.5)	1 (0.1)
OTHER VIRAL VACCINES	7 (1.3)	1 (0.5)	8 (1.1)
TOZINAMERAN	6 (1.1)	0	6 (0.8)
COVID-19 VACCINE	1 (0.2)	0	1 (0.1)
COVID-19 VACCINE mRNA (MRNA 1273)	1 (0.2)	1 (0.5)	2 (0.3)
OXAZOL, THIAZINE, AND TRIAZINE DERIVATIVES	1 (0.2)	0	1 (0.1)
METAXALONE	1 (0.2)	0	1 (0.1)
OXICAMS	5 (0.9)	6 (2.9)	11 (1.5)
MELOXICAM	5 (0.9)	6 (2.9)	11 (1.5)
PARAMAGNETIC CONTRAST MEDIA	0	1 (0.5)	1 (0.1)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGMT-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
PARAMAGNETIC CONTRAST MEDIA (Continued)			
GADOBUTROL	0	1 (0.5)	1 (0.1)
PARASYMPATHOMIMETICS	1 (0.2)	0	1 (0.1)
PILOCARPINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
PENICILLINS WITH EXTENDED SPECTRUM	35 (6.6)	5 (2.4)	40 (5.4)
AMOXICILLIN	28 (5.3)	4 (2.0)	32 (4.4)
AMOXICILLIN TRIHYDRATE	3 (0.6)	1 (0.5)	4 (0.5)
PIVMECILLINAM	3 (0.6)	0	3 (0.4)
AMPICILLIN	2 (0.4)	0	2 (0.3)
PERIPHERAL OPIOID RECEPTOR ANTAGONISTS	2 (0.4)	0	2 (0.3)
NALOXEGOL OXALATE	2 (0.4)	0	2 (0.3)
PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN	1 (0.2)	2 (1.0)	3 (0.4)
CHLORPROMAZINE	1 (0.2)	0	1 (0.1)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN (Continued)			
LEVOMEPEMORAZINE	0	2 (1.0)	2 (0.3)
PHENOTHIAZINES WITH PIPERAZINE STRUCTURE			
PROCHLORPERAZINE MALEATE	2 (0.4) 2 (0.4)	0 0	2 (0.3) 2 (0.3)
PHENYLALKYLAMINE DERIVATIVES			
VERAPAMIL	3 (0.6) 3 (0.6)	1 (0.5) 1 (0.5)	4 (0.5) 4 (0.5)
PHENYLPIPERIDINE DERIVATIVES			
FENTANYL FENTANYL CITRATE	41 (7.8) 40 (7.6) 3 (0.6)	16 (7.8) 16 (7.8) 1 (0.5)	57 (7.8) 56 (7.6) 4 (0.5)
PIPERAZINE DERIVATIVES			
CETIRIZINE HYDROCHLORIDE CETIRIZINE MECLOZINE	28 (5.3) 13 (2.5) 7 (1.3) 5 (0.9)	11 (5.4) 4 (2.0) 5 (2.4) 1 (0.5)	39 (5.3) 17 (2.3) 12 (1.6) 6 (0.8)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
PIPERAZINE DERIVATIVES (Continued)			
HYDROXYZINE	2 (0.4)	0	2 (0.3)
LEVO CETIRIZINE DIHYDROCHLORIDE	2 (0.4)	0	2 (0.3)
HYDROXYZINE HYDROCHLORIDE	1 (0.2)	1 (0.5)	2 (0.3)
LEVO CETIRIZINE	1 (0.2)	0	1 (0.1)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN			
ACETYLSALICYLIC ACID	137 (25.9)	48 (23.4)	185 (25.2)
ACETYLSALICYLATE LYSINE	119 (22.5)	42 (20.5)	161 (21.9)
CLOPIDOGREL	12 (2.3)	4 (2.0)	16 (2.2)
CLOPIDOGREL BISULFATE	8 (1.5)	2 (1.0)	10 (1.4)
ACETYLSALICYLATE CALCIUM	8 (1.5)	6 (2.9)	14 (1.9)
CARBASALATE CALCIUM	1 (0.2)	0	1 (0.1)
CILOSTAZOL	1 (0.2)	0	1 (0.1)
CLOPIDOGREL HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
DIPYRIDAMOLE	1 (0.2)	0	1 (0.1)
TICAGRELOR	1 (0.2)	0	1 (0.1)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
PLATINUM COMPOUNDS	1 (0.2)	0	1 (0.1)
CARBOPLATIN	1 (0.2)	0	1 (0.1)
PNEUMOCOCCAL VACCINES	2 (0.4)	0	2 (0.3)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	1 (0.2)	0	1 (0.1)
PNEUMOCOCCAL VACCINE POLYV	1 (0.2)	0	1 (0.1)
POLY (ADP-RIBOSE) POLYMERASE (PARP) INHIBITORS	1 (0.2)	1 (0.5)	2 (0.3)
OLAPARIB	1 (0.2)	1 (0.5)	2 (0.3)
POTASSIUM	67 (12.7)	17 (8.3)	84 (11.4)
POTASSIUM CHLORIDE	50 (9.5)	12 (5.9)	62 (8.4)
POTASSIUM	10 (1.9)	4 (2.0)	14 (1.9)
POTASSIUM PHOSPHATE MONOBASIC	6 (1.1)	2 (1.0)	8 (1.1)
POTASSIUM CITRATE	2 (0.4)	0	2 (0.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
POTASSIUM (Continued)			
POTASSIUM GLUCONATE	2 (0.4)	0	2 (0.3)
POTASSIUM BICARBONATE	1 (0.2)	0	1 (0.1)
POTASSIUM PHOSPHATE DIBASIC	1 (0.2)	0	1 (0.1)
PREGNADIEN DERIVATIVES	0	1 (0.5)	1 (0.1)
MEGESTROL ACETATE	0	1 (0.5)	1 (0.1)
PREPARATIONS INCREASING URIC ACID EXCRETION	2 (0.4)	0	2 (0.3)
PROBENECID	2 (0.4)	0	2 (0.3)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	33 (6.2)	9 (4.4)	42 (5.7)
ALLOPURINOL	32 (6.0)	9 (4.4)	41 (5.6)
FEBUXOSTAT	1 (0.2)	0	1 (0.1)
PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM	5 (0.9)	1 (0.5)	6 (0.8)
COLCHICINE	5 (0.9)	1 (0.5)	6 (0.8)

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
PREPARATIONS WITH SALICYLIC ACID DERIVATIVES	0	1 (0.5)	1 (0.1)
METHYL SALICYLATE	0	1 (0.5)	1 (0.1)
PROGESTOGENS	4 (0.8)	2 (1.0)	6 (0.8)
MEDROXYPROGESTERONE ACETATE	2 (0.4)	0	2 (0.3)
MEDROXYPROGESTERONE	1 (0.2)	0	1 (0.1)
MEGESTROL	1 (0.2)	2 (1.0)	3 (0.4)
PROLACTINE INHIBITORS	1 (0.2)	1 (0.5)	2 (0.3)
CABERGOLINE	1 (0.2)	1 (0.5)	2 (0.3)
PROPIONIC ACID DERIVATIVES	146 (27.6)	56 (27.3)	202 (27.5)
IBUPROFEN	99 (18.7)	42 (20.5)	141 (19.2)
NAPROXEN	27 (5.1)	10 (4.9)	37 (5.0)
NAPROXEN SODIUM	25 (4.7)	6 (2.9)	31 (4.2)

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Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
PROPIONIC ACID DERIVATIVES (Continued)			
KETOPROFEN	3 (0.6)	1 (0.5)	4 (0.5)
IBUPROFEN;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
PROPULSIVES			
METOCLOPRAMIDE	74 (14.0)	14 (6.8)	88 (12.0)
METOCLOPRAMIDE HYDROCHLORIDE	33 (6.2)	6 (2.9)	39 (5.3)
DOMPERIDONE	29 (5.5)	5 (2.4)	34 (4.6)
ALIZAPRIDE	11 (2.1)	1 (0.5)	12 (1.6)
ALIZAPRIDE HYDROCHLORIDE	4 (0.8)	2 (1.0)	6 (0.8)
ALIZAPRIDE HYDROCHLORIDE	1 (0.2)	1 (0.5)	2 (0.3)
PROSTAGLANDIN ANALOGUES			
LATANOPROST	13 (2.5)	3 (1.5)	16 (2.2)
BIMATOPROST	10 (1.9)	0	10 (1.4)
TRAVOPROST	3 (0.6)	1 (0.5)	4 (0.5)
TRAVOPROST	1 (0.2)	2 (1.0)	3 (0.4)
PROTON PUMP INHIBITORS			
	186 (35.2)	84 (41.0)	270 (36.8)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
PROTON PUMP INHIBITORS (Continued)			
OMEPRAZOLE	84 (15.9)	38 (18.5)	122 (16.6)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	33 (6.2)	10 (4.9)	43 (5.9)
PANTOPRAZOLE	29 (5.5)	21 (10.2)	50 (6.8)
ESOMEPRAZOLE	22 (4.2)	4 (2.0)	26 (3.5)
LANSOPRAZOLE	19 (3.6)	8 (3.9)	27 (3.7)
ESOMEPRAZOLE MAGNESIUM	6 (1.1)	5 (2.4)	11 (1.5)
DEXLANSOPRAZOLE	5 (0.9)	2 (1.0)	7 (1.0)
RABEPRAZOLE SODIUM	2 (0.4)	0	2 (0.3)
RABEPRAZOLE	1 (0.2)	0	1 (0.1)
PROTON PUMP INHIBITORS	0	1 (0.5)	1 (0.1)
PURINE ANALOGUES			
MERCAPTOPURINE	0	1 (0.5)	1 (0.1)
PURINE DERIVATIVES			
PENTOXIFYLLINE	5 (0.9)	0	5 (0.7)
	5 (0.9)	0	5 (0.7)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
PYRAZOLONES	1 (0.2)	0	1 (0.1)
METAMIZOLE SODIUM	1 (0.2)	0	1 (0.1)
PYRIMIDINE ANALOGUES	0	1 (0.5)	1 (0.1)
FLUOROURACIL	0	1 (0.5)	1 (0.1)
QUININE AND DERIVATIVES	1 (0.2)	0	1 (0.1)
QUININE SULFATE	1 (0.2)	0	1 (0.1)
RENIN-INHIBITORS	1 (0.2)	1 (0.5)	2 (0.3)
ALISKIREN FUMARATE	1 (0.2)	1 (0.5)	2 (0.3)
RETINOIDS FOR TREATMENT OF PSORIASIS	1 (0.2)	0	1 (0.1)
ACITRETIN	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
SALICYLIC ACID AND DERIVATIVES	9 (1.7)	2 (1.0)	11 (1.5)
ACETYLSALICYLIC ACID	5 (0.9)	2 (1.0)	7 (1.0)
ACETYLSALICYLIC ACID;CAFFEINE	2 (0.4)	0	2 (0.3)
ACETYLSALICYLIC ACID;CITRIC ACID;SODIUM BICARBONATE	2 (0.4)	0	2 (0.3)
SALICYLIC ACID PREPARATIONS	1 (0.2)	0	1 (0.1)
MENTHOL;METHYL SALICYLATE	1 (0.2)	0	1 (0.1)
SECOND-GENERATION CEPHALOSPORINS	7 (1.3)	0	7 (1.0)
CEFUROXIME	4 (0.8)	0	4 (0.5)
CEFUROXIME AXETIL	2 (0.4)	0	2 (0.3)
CEFUROXIME SODIUM	1 (0.2)	0	1 (0.1)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	34 (6.4)	7 (3.4)	41 (5.6)
SALBUTAMOL	24 (4.5)	5 (2.4)	29 (4.0)
SALBUTAMOL SULFATE	8 (1.5)	2 (1.0)	10 (1.4)
FORMOTEROL	1 (0.2)	0	1 (0.1)
FORMOTEROL FUMARATE	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
SELECTIVE BETA-2-ADRENOCEPTOR AGONISTS (Continued)			
SALMETEROL	1 (0.2)	0	1 (0.1)
SELECTIVE IMMUNOSUPPRESSANTS			
APREMILAST	0	1 (0.5)	1 (0.1)
	0	1 (0.5)	1 (0.1)
SELECTIVE SEROTONIN (5HT1) AGONISTS			
SUMATRIPTAN	2 (0.4)	1 (0.5)	3 (0.4)
SUMATRIPTAN SUCCINATE	1 (0.2)	0	1 (0.1)
RIZATRIPTAN	1 (0.2)	0	1 (0.1)
	0	1 (0.5)	1 (0.1)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS			
SERTRALINE	40 (7.6)	15 (7.3)	55 (7.5)
ESCITALOPRAM OXALATE	10 (1.9)	6 (2.9)	16 (2.2)
CITALOPRAM	8 (1.5)	0	8 (1.1)
PAROXETINE	6 (1.1)	2 (1.0)	8 (1.1)
SERTRALINE HYDROCHLORIDE	4 (0.8)	1 (0.5)	5 (0.7)
	4 (0.8)	0	4 (0.5)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS (Continued)			
CITALOPRAM HYDROBROMIDE	3 (0.6)	0	3 (0.4)
ESCITALOPRAM	3 (0.6)	3 (1.5)	6 (0.8)
FLUOXETINE HYDROCHLORIDE	2 (0.4)	1 (0.5)	3 (0.4)
FLUOXETINE	1 (0.2)	0	1 (0.1)
PAROXETINE HYDROCHLORIDE	1 (0.2)	3 (1.5)	4 (0.5)
SELENIUM	3 (0.6)	0	3 (0.4)
SELENIUM	3 (0.6)	0	3 (0.4)
SEROTONIN (5HT3) ANTAGONISTS	271 (51.2)	37 (18.0)	308 (42.0)
ONDANSETRON	263 (49.7)	34 (16.6)	297 (40.5)
ONDANSETRON HYDROCHLORIDE	7 (1.3)	2 (1.0)	9 (1.2)
GRANisetron	4 (0.8)	1 (0.5)	5 (0.7)
GRANisetron HYDROCHLORIDE	4 (0.8)	2 (1.0)	6 (0.8)
PALONOSETRON HYDROCHLORIDE	4 (0.8)	0	4 (0.5)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
SILICONE PRODUCTS	0	1 (0.5)	1 (0.1)
CASTOR OIL, HYDROGENATED;CYCLOMETHICONE	0	1 (0.5)	1 (0.1)
5;DIMETHICONOL;ETHYLHEXYL PALMITATE;TOCOPHERYL ACETATE			
SILVER COMPOUNDS	2 (0.4)	1 (0.5)	3 (0.4)
SILVER NITRATE	2 (0.4)	0	2 (0.3)
CARMELLOSE SODIUM;SILVER	0	1 (0.5)	1 (0.1)
SODIUM	3 (0.6)	1 (0.5)	4 (0.5)
SODIUM CHLORIDE	3 (0.6)	1 (0.5)	4 (0.5)
SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS	5 (0.9)	1 (0.5)	6 (0.8)
EMPAGLIFLOZIN	4 (0.8)	1 (0.5)	5 (0.7)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	1 (0.2)	0	1 (0.1)
SOFT PARAFFIN AND FAT PRODUCTS	1 (0.2)	2 (1.0)	3 (0.4)
WHITE SOFT PARAFFIN	1 (0.2)	0	1 (0.1)
PARAFFIN, LIQUID	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
SOFT PARAFFIN AND FAT PRODUCTS (Continued)			
PARAFFIN, LIQUID;WOOL ALCOHOLS	0	1 (0.5)	1 (0.1)
SOFTENERS, EMOLLIENTS	56 (10.6)	19 (9.3)	75 (10.2)
DOCUSATE SODIUM	43 (8.1)	15 (7.3)	58 (7.9)
DOCUSATE	12 (2.3)	4 (2.0)	16 (2.2)
DOCUSATE CALCIUM	1 (0.2)	0	1 (0.1)
PARAFFIN, LIQUID	1 (0.2)	0	1 (0.1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	17 (3.2)	1 (0.5)	18 (2.5)
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE	12 (2.3)	1 (0.5)	13 (1.8)
ELECTROLYTES NOS	2 (0.4)	0	2 (0.3)
GLUCOSE;SODIUM CHLORIDE	2 (0.4)	0	2 (0.3)
SODIUM CHLORIDE	2 (0.4)	0	2 (0.3)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE	1 (0.2)	0	1 (0.1)
HEXAhydrate;POTASSIUM CHLORIDE;SODIUM ACETATE			
TRIhydrate;SODIUM CHLORIDE			

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE (Continued)			
GLUCONATE SODIUM;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE GLUCOSE;POTASSIUM CHLORIDE	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
SOLUTIONS FOR PARENTERAL NUTRITION	9 (1.7)	1 (0.5)	10 (1.4)
GLUCOSE	6 (1.1)	1 (0.5)	7 (1.0)
AMINO ACIDS NOS	2 (0.4)	0	2 (0.3)
SOLUTIONS FOR PARENTERAL NUTRITION	1 (0.2)	0	1 (0.1)
SOLUTIONS PRODUCING OSMOTIC DIURESIS	1 (0.2)	0	1 (0.1)
MANNITOL	1 (0.2)	0	1 (0.1)
SOMATOSTATIN AND ANALOGUES	0	1 (0.5)	1 (0.1)
OCTREOTIDE	0	1 (0.5)	1 (0.1)
STREPTOGRAMINS	0	1 (0.5)	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
STREPTOGRAMINS (Continued)			
PRISTINAMYCIN	0	1 (0.5)	1 (0.1)
SUBSTITUTED ALKYLAMINES			
CHLORPHENAMINE	1 (0.2)	1 (0.5)	2 (0.3)
CHLORPHENAMINE MALEATE	1 (0.2)	0	1 (0.1)
CHLORPHENAMINE MALEATE	0	1 (0.5)	1 (0.1)
SULFONAMIDES			
SULFADIAZINE SILVER	1 (0.2)	0	1 (0.1)
SULFADIAZINE SILVER	1 (0.2)	0	1 (0.1)
SULFONAMIDES, PLAIN			
FUROSEMIDE	80 (15.1)	33 (16.1)	113 (15.4)
CHLORTALIDONE	71 (13.4)	30 (14.6)	101 (13.8)
BUMETANIDE	5 (0.9)	1 (0.5)	6 (0.8)
INDAPAMIDE	4 (0.8)	2 (1.0)	6 (0.8)
TORASEMIDE	2 (0.4)	1 (0.5)	3 (0.4)
TORASEMIDE	1 (0.2)	1 (0.5)	2 (0.3)

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
SULFONYLUREAS	23 (4.3)	10 (4.9)	33 (4.5)
GLIPIZIDE	10 (1.9)	2 (1.0)	12 (1.6)
GLIMEPIRIDE	8 (1.5)	7 (3.4)	15 (2.0)
GLICLAZIDE	4 (0.8)	0	4 (0.5)
GLIBENCLAMIDE	2 (0.4)	1 (0.5)	3 (0.4)
SYMPATHOMIMETICS	8 (1.5)	1 (0.5)	9 (1.2)
PSEUDOEPHEDRINE HYDROCHLORIDE	4 (0.8)	1 (0.5)	5 (0.7)
PSEUDOEPHEDRINE	3 (0.6)	0	3 (0.4)
BROMPHENIRAMINE MALEATE;PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
LORATADINE;PSEUDOEPHEDRINE SULFATE	1 (0.2)	0	1 (0.1)
SYMPATHOMIMETICS IN GLAUCOMA THERAPY	2 (0.4)	2 (1.0)	4 (0.5)
BRIMONIDINE	2 (0.4)	0	2 (0.3)
BRIMONIDINE TARTRATE	0	2 (1.0)	2 (0.3)
SYMPATHOMIMETICS USED AS DECONGESTANTS	1 (0.2)	0	1 (0.1)
TETRYZOLINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
SYMPATHOMIMETICS, PLAIN OXYMETAZOLINE	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP DICYCLOVERINE	2 (0.4) 2 (0.4)	0 0	2 (0.3) 2 (0.3)
SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS GLYCOPYRRONIUM BROMIDE	3 (0.6) 3 (0.6)	0 0	3 (0.4) 3 (0.4)
TAXANES CABAZITAXEL DOCETAXEL	4 (0.8) 3 (0.6) 1 (0.2)	1 (0.5) 1 (0.5) 0	5 (0.7) 4 (0.5) 1 (0.1)
TECHNETIUM (99MTC) COMPOUNDS TECHNETIUM TC 99M MEDRONATE	2 (0.4) 2 (0.4)	1 (0.5) 1 (0.5)	3 (0.4) 3 (0.4)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
TECHNETIUM (99MTC) COMPOUNDS (Continued)			
SODIUM PERTECHNETATE (99M TC)	1 (0.2)	0	1 (0.1)
TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	16 (3.0)	11 (5.4)	27 (3.7)
DUTASTERIDE	9 (1.7)	4 (2.0)	13 (1.8)
FINASTERIDE	7 (1.3)	7 (3.4)	14 (1.9)
TETANUS VACCINES	2 (0.4)	0	2 (0.3)
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	1 (0.2)	0	1 (0.1)
TETANUS VACCINES	1 (0.2)	0	1 (0.1)
TETRACYCLINES	9 (1.7)	3 (1.5)	12 (1.6)
DOXYCYCLINE	7 (1.3)	1 (0.5)	8 (1.1)
DOXYCYCLINE HYCLATE	2 (0.4)	1 (0.5)	3 (0.4)
MINOCYCLINE	1 (0.2)	0	1 (0.1)
DEMECLOCYCLINE	0	1 (0.5)	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
THIAZIDES AND POTASSIUM IN COMBINATION	2 (0.4)	2 (1.0)	4 (0.5)
BENDROFLUMETHIAZIDE;POTASSIUM	1 (0.2)	1 (0.5)	2 (0.3)
BENDROFLUMETHIAZIDE;POTASSIUM CHLORIDE	1 (0.2)	1 (0.5)	2 (0.3)
THIAZIDES, PLAIN	25 (4.7)	9 (4.4)	34 (4.6)
HYDROCHLOROTHIAZIDE	25 (4.7)	9 (4.4)	34 (4.6)
THIAZOLIDINEDIONES	3 (0.6)	2 (1.0)	5 (0.7)
PIOGLITAZONE	2 (0.4)	2 (1.0)	4 (0.5)
PIOGLITAZONE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
THIRD-GENERATION CEPHALOSPORINS	25 (4.7)	6 (2.9)	31 (4.2)
CEFTRIAXONE	11 (2.1)	5 (2.4)	16 (2.2)
CEFTRIAXONE SODIUM	10 (1.9)	1 (0.5)	11 (1.5)
CEFDINIR	5 (0.9)	1 (0.5)	6 (0.8)
CEFIXIME	1 (0.2)	0	1 (0.1)
CEFOTAXIME SODIUM	1 (0.2)	0	1 (0.1)
CEFPODOXIME	1 (0.2)	0	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
THYROID HORMONES	54 (10.2)	15 (7.3)	69 (9.4)
LEVOTHYROXINE	35 (6.6)	6 (2.9)	41 (5.6)
LEVOTHYROXINE SODIUM	19 (3.6)	9 (4.4)	28 (3.8)
LIOTHYRONINE	1 (0.2)	0	1 (0.1)
THYROID	1 (0.2)	0	1 (0.1)
LIOTHYRONINE SODIUM	0	1 (0.5)	1 (0.1)
TRIAZOLE DERIVATIVES	7 (1.3)	2 (1.0)	9 (1.2)
FLUCONAZOLE	7 (1.3)	2 (1.0)	9 (1.2)
TRIMETHOPRIM AND DERIVATIVES	2 (0.4)	0	2 (0.3)
TRIMETHOPRIM	2 (0.4)	0	2 (0.3)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0.2)	1 (0.5)	2 (0.3)
ADALIMUMAB	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS (Continued)			
ETANERCEPT	0	1 (0.5)	1 (0.1)
URINARY CONCREMENT SOLVENTS			
SODIUM BICARBONATE	2 (0.4)	0	2 (0.3)
VARICELLA ZOSTER VACCINES			
VARICELLA ZOSTER VACCINE RGE (CHO)	2 (0.4)	0	1 (0.1)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS			
UBIDECARENONE	1 (0.2)	0	1 (0.1)
PHOSPHORUS	1 (0.2)	0	1 (0.1)
ANETHOLE TRITHIONE	1 (0.2)	0	1 (0.1)
SODIUM BICARBONATE	1 (0.2)	0	1 (0.1)
UBIQUINOL	1 (0.2)	0	1 (0.1)
ACETYL-L-CARNITINE ARGINATE DIHYDROCHLORIDE;THIOCTIC ACID	1 (0.2)	0	1 (0.1)
FUCOIDAN	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS (Continued)			
QUERCETIN	1 (0.2)	0	1 (0.1)
THIOCTIC ACID	1 (0.2)	0	1 (0.1)
PROBIOTICS NOS	0	1 (0.5)	1 (0.1)
VITAMIN A AND D IN COMBINATION	1 (0.2)	0	1 (0.1)
HALIBUT-LIVER OIL	1 (0.2)	0	1 (0.1)
VITAMIN A, PLAIN	2 (0.4)	0	2 (0.3)
RETINOL	2 (0.4)	0	2 (0.3)
VITAMIN B-COMPLEX WITH MINERALS	0	1 (0.5)	1 (0.1)
IRON;VITAMIN B COMPLEX	0	1 (0.5)	1 (0.1)
VITAMIN B-COMPLEX WITH VITAMIN C	4 (0.8)	2 (1.0)	6 (0.8)
ASCORBIC ACID;VITAMIN B COMPLEX	3 (0.6)	1 (0.5)	4 (0.5)
ASCORBIC ACID;FOLIC ACID;VITAMIN B NOS	1 (0.2)	0	1 (0.1)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
VITAMIN B-COMPLEX WITH VITAMIN C (Continued) ASCORBIC ACID;CALCIUM PANTOTHENATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	0	1 (0.5)	1 (0.1)
VITAMIN B-COMPLEX, PLAIN VITAMIN B COMPLEX BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	11 (2.1) 11 (2.1) 1 (0.2)	9 (4.4) 9 (4.4) 0	20 (2.7) 20 (2.7) 1 (0.1)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12 CYANOCOBALAMIN;PYRIDOXINE;THIAMINE PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	3 (0.6) 2 (0.4) 1 (0.2)	0 0 0	3 (0.4) 2 (0.3) 1 (0.1)
VITAMIN B1, PLAIN THIAMINE THIAMINE HYDROCHLORIDE	4 (0.8) 2 (0.4) 2 (0.4)	0 0 0	4 (0.5) 2 (0.3) 2 (0.3)

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Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	41 (7.8)	24 (11.7)	65 (8.9)
CYANOCOBALAMIN	35 (6.6)	21 (10.2)	56 (7.6)
VITAMIN B12 NOS	6 (1.1)	1 (0.5)	7 (1.0)
HYDROXOCOBALAMIN	0	2 (1.0)	2 (0.3)
VITAMIN D AND ANALOGUES	178 (33.6)	62 (30.2)	240 (32.7)
COLECALCIFEROL	115 (21.7)	40 (19.5)	155 (21.1)
VITAMIN D NOS	52 (9.8)	23 (11.2)	75 (10.2)
ERGOCALCIFEROL	9 (1.7)	3 (1.5)	12 (1.6)
ALFACALCIDOL	4 (0.8)	0	4 (0.5)
CALCITRIOL	2 (0.4)	0	2 (0.3)
VITAMIN K	3 (0.6)	1 (0.5)	4 (0.5)
PHYTOMENADIONE	2 (0.4)	0	2 (0.3)
MENAQUINONE	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
VITAMIN K (Continued)			
VITAMIN K NOS	0	1 (0.5)	1 (0.1)
VITAMIN K ANTAGONISTS			
WARFARIN	10 (1.9)	6 (2.9)	16 (2.2)
ACENOCOUMAROL	7 (1.3)	2 (1.0)	9 (1.2)
PHENPROCOUMON	1 (0.2)	0	1 (0.1)
WARFARIN SODIUM	1 (0.2)	1 (0.5)	2 (0.3)
WARFARIN SODIUM	1 (0.2)	3 (1.5)	4 (0.5)
VITAMINS WITH MINERALS			
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE	11 (2.1)	5 (2.4)	16 (2.2)
MINERALS NOS;VITAMINS NOS	3 (0.6)	1 (0.5)	4 (0.5)
ASCORBIC ACID;BETACAROTENE;COPPER;TOCOFERSOLAN;ZINC			
ASCORBIC ACID;BETACAROTENE;MANGANESE	3 (0.6)	2 (1.0)	5 (0.7)
GLUCONATE;NICOTINAMIDE;SELENIUM;TOCOPHERYL ACETATE;ZINC GLUCONATE	1 (0.2)	1 (0.5)	2 (0.3)
GLUCONATE;NICOTINAMIDE;SELENIUM;TOCOPHERYL ACETATE;ZINC GLUCONATE	1 (0.2)	0	1 (0.1)

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Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ASCORBIC ACID;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIUM;CYANOCOBALAMIN;FOLIC ACID;MAGNESIUM CARBONATE;MAGNESIUM HYDROXIDE;MANGANESE GLUCONATE;NICOTINIC ACID;POTASSIUM	1 (0.2)	0	1 (0.1)
ASCORBIC ACID;CHROMIUM;COPPER;FOLIC ACID;INOSITOL;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;POTASSIUM;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;VITAMIN B1 NOS;VITAMIN B12	1 (0.2)	0	1 (0.1)
VITAMINS WITH MINERALS	1 (0.2)	0	1 (0.1)
ASCORBIC ACID;BETACAROTENE;SELENIUM;TOCOPHEROL	0	1 (0.5)	1 (0.1)
VITAMINS, OTHER COMBINATIONS	3 (0.6)	3 (1.5)	6 (0.8)
VITAMINS, OTHER COMBINATIONS	2 (0.4)	2 (1.0)	4 (0.5)
ASCORBIC ACID;CUPRIC OXIDE;TOCOPHERYL ACETATE;XANTOFYL;ZINC OXIDE	1 (0.2)	0	1 (0.1)
BIOFLAVONOIDS NOS;VITAMINS NOS	0	1 (0.5)	1 (0.1)
WART AND ANTI-CORN PREPARATIONS	1 (0.2)	0	1 (0.1)
SALICYLIC ACID	1 (0.2)	0	1 (0.1)

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7 Concomitant medications during randomized treatment (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA IOPAMIDOL	2 (0.4) 2 (0.4)	2 (1.0) 2 (1.0)	4 (0.5) 4 (0.5)
XANTHINE DERIVATIVES CAFFEINE	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
ZINC ZINC ZINC GLUCONATE	8 (1.5) 7 (1.3) 1 (0.2)	0 0 0	8 (1.1) 7 (1.0) 1 (0.1)
ZINC PRODUCTS CALAMINE;MENTHOL;ZINC OXIDE MENTHOL;ZINC OXIDE PARAFFIN SOFT;PARAFFIN, LIQUID;ZINC OXIDE ZINC OXIDE	4 (0.8) 1 (0.2) 1 (0.2) 1 (0.2) 1 (0.2)	0 0 0 0 0	4 (0.5) 1 (0.1) 1 (0.1) 1 (0.1) 1 (0.1)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-7 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Number of patients with at least one concomitant medication	30 (100)
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS AMLODIPINE BESILATE;RAMIPRIL	1 (3.3) 1 (3.3)
ACE INHIBITORS, PLAIN RAMIPRIL	4 (13.3) 4 (13.3)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES DICLOFENAC	2 (6.7) 2 (6.7)
ACIDIFIERS METHIONINE	1 (3.3) 1 (3.3)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS FLUTICASONE PROPIONATE;FORMOTEROL FUMARATE	1 (3.3) 1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	2 (6.7)
FENOTEROL HYDROBROMIDE;IPRATROPIUM BROMIDE	1 (3.3)
GLYCOPYRRONIUM BROMIDE;INDACATEROL MALEATE	1 (3.3)
UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	1 (3.3)
ALDOSTERONE ANTAGONISTS	1 (3.3)
SPIRONOLACTONE	1 (3.3)
ALPHA-ADRENORECEPTOR ANTAGONISTS	4 (13.3)
TAMSULOSIN	3 (10.0)
TAMSULOSIN HYDROCHLORIDE	1 (3.3)
AMINO ACIDS AND DERIVATIVES	1 (3.3)
LEVOCARNITINE	1 (3.3)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (3.3)
MESALAZINE	1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND CALCIUM CHANNEL BLOCKERS	1 (3.3)
AMLODIPINE BESILATE;VALSARTAN	1 (3.3)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS	1 (3.3)
HYDROCHLOROTHIAZIDE;TELMISARTAN	1 (3.3)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	11 (36.7)
CANDESARTAN	6 (20.0)
LOSARTAN	2 (6.7)
VALSARTAN	2 (6.7)
OLMESARTAN	1 (3.3)
ANTI-ANDROGENS	11 (36.7)
ENZALUTAMIDE	10 (33.3)
BICALUTAMIDE	1 (3.3)
ANTIBIOTICS	1 (3.3)
NYSTATIN;ZINC OXIDE	1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
ANTIDIARRHEAL MICROORGANISMS ASCORBIC ACID;BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS LACTIS;LACTOBACILLUS RHAMNOSUS;MAGNESIUM SALTS	1 (3.3) 1 (3.3)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT AMPHOTERICIN B	1 (3.3) 1 (3.3)
ASCORBIC ACID (VITAMIN C), PLAIN ASCORBIC ACID	1 (3.3) 1 (3.3)
BENZODIAZEPINE DERIVATIVES BROMAZEPAM OXAZEPAM	2 (6.7) 1 (3.3) 1 (3.3)
BENZODIAZEPINE RELATED DRUGS ZOPICLONE	3 (10.0) 3 (10.0)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHODrug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
BETA BLOCKING AGENTS, SELECTIVE BISOPROLOL METOPROLOL SUCCINATE METOPROLOL NEBIVOLOL	13 (43.3) 9 (30.0) 2 (6.7) 1 (3.3) 1 (3.3)
BETA-LACTAMASE INHIBITORS TAZOBACTAM	1 (3.3) 1 (3.3)
BIGUANIDES METFORMIN METFORMIN HYDROCHLORIDE	5 (16.7) 4 (13.3) 1 (3.3)
BIGUANIDES AND AMIDINES CHLORHEXIDINE	1 (3.3) 1 (3.3)
BISPHOSPHONATES ZOLEDRONIC ACID ZOLEDRONIC ACID MONOHYDRATE	3 (10.0) 2 (6.7) 1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO DRUG Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
CALCIUM	7 (23.3)
CALCIUM	3 (10.0)
CALCIUM CARBONATE	3 (10.0)
CALCIUM CARBONATE;CALCIUM LACTATE GLUCONATE	1 (3.3)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	5 (16.7)
CALCIUM CARBONATE;COLECALCIFEROL	3 (10.0)
CALCIUM;VITAMIN D NOS	2 (6.7)
CARBAPENEMS	2 (6.7)
MEROPENEM	1 (3.3)
MEROPENEM TRIHYDRATE	1 (3.3)
COLONY STIMULATING FACTORS	2 (6.7)
GRANULOCYTE COLONY STIMULATING FACTOR	1 (3.3)
LIPEGFILGRASTIM	1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE	1 (3.3) 1 (3.3)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM PIPERACILLIN SODIUM;TAZOBACTAM SODIUM SULTAMICILLIN SULTAMICILLIN TOSILATE	4 (13.3) 2 (6.7) 1 (3.3) 1 (3.3) 1 (3.3)
CONTACT LAXATIVES BISACODYL SODIUM PICOSULFATE	3 (10.0) 2 (6.7) 1 (3.3)
COXIBS CELECOXIB	2 (6.7) 1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO DRUG Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
COXIBS (Continued) ETORICOXIB	1 (3.3)
DIHYDROPYRIDINE DERIVATIVES AMLODIPINE	5 (16.7) 2 (6.7)
LERCANIDIPINE	2 (6.7)
LERCANIDIPINE HYDROCHLORIDE	1 (3.3)
Dipeptidyl Peptidase 4 (DPP-4) INHIBITORS SAXAGLIPTIN HYDROCHLORIDE	1 (3.3) 1 (3.3)
DIPHENYLPROPYLAMINE DERIVATIVES LEVOMETHADONE HYDROCHLORIDE	3 (10.0) 1 (3.3)
METHADONE HYDROCHLORIDE	1 (3.3)
PIRITRAMIDE	1 (3.3)
DIRECT FACTOR XA INHIBITORS APIXABAN	6 (20.0) 5 (16.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

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Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

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Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
DIRECT FACTOR XA INHIBITORS (Continued) RIVAROXABAN	2 (6.7)
DOPA AND DOPA DERIVATIVES LEVODOPA	1 (3.3) 1 (3.3)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE TROSPiUM CHLORIDE	1 (3.3) 1 (3.3)
ELECTROLYTE SOLUTIONS SODIUM CHLORIDE	9 (30.0) 9 (30.0)
ENEMAS BISACODYL	2 (6.7) 2 (6.7)
ENZYME PREPARATIONS PANCREATiN;SIMETiCONE	1 (3.3) 1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

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Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
FLUOROQUINOLOONES CIPROFLOXACIN	2 (6.7) 2 (6.7)
FOLIC ACID AND DÉRIVATIVES FOLIC ACID	1 (3.3) 1 (3.3)
GLUCOCORTICOIDS DEXAMETHASONE PREDNISOLONE BUDESONIDE PREDNISONE	16 (53.3) 10 (33.3) 8 (26.7) 1 (3.3) 1 (3.3)
GONADOTROPIN RELEASING HORMONE ANALOGUES LEUPRORELIN ACETATE LEUPRORELIN TRIPTORELIN EMBONATE BUSERELIN GONADOTROPIN RELEASING HORMONE ANALOGUES BUSERELIN ACETATE	27 (90.0) 10 (33.3) 9 (30.0) 3 (10.0) 2 (6.7) 2 (6.7) 1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO DRUG Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
GONADOTROPIN-RELEASING HORMONES GONADORELIN DIACETATE TETRAHYDRATE	1 (3.3) 1 (3.3)
HEPARIN GROUP ENOXAPARIN SODIUM CERTOPARIN SODIUM	3 (10.0) 2 (6.7) 1 (3.3)
HMG COA REDUCTASE INHIBITORS ATORVASTATIN SIMVASTATIN	9 (30.0) 7 (23.3) 2 (6.7)
IMIDAZOLE AND TRIAZOLE DERIVATIVES FLUPREDNIDENE ACETATE;MICONAZOLE NITRATE	1 (3.3) 1 (3.3)
IMIDAZOLINE RECEPTOR AGONISTS MOXONIDINE	2 (6.7) 2 (6.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHODrug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	3 (10.0)
INSULIN	1 (3.3)
INSULIN ASPART	1 (3.3)
INSULIN HUMAN	1 (3.3)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	1 (3.3)
INSULIN GLARGINE	1 (3.3)
LINCOSAMIDES	2 (6.7)
CLINDAMYCIN	2 (6.7)
MAGNESIUM	3 (10.0)
MAGNESIUM	3 (10.0)
NATURAL OPIUM ALKALOIDS	8 (26.7)
HYDROMORPHONE	5 (16.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHODrug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoc (N=30) n (%)
NATURAL OPIUM ALKALOIDS (Continued)	
HYDROMORPHONE HYDROCHLORIDE	3 (10.0)
OXYCODONE HYDROCHLORIDE	3 (10.0)
MORPHINE SULFATE	1 (3.3)
NALOXONE HYDROCHLORIDE;OXYCODONE HYDROCHLORIDE	1 (3.3)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	
DOXEPIN	1 (3.3) 1 (3.3)
NOT CODED	
CORDYCEPS SINENSIS	2 (6.7) 1 (3.3)
GALIUM APARINE HERB;STILLINGIA SYLVATICA ROOT;TRIFOLIUM PRATENSE FLOWER;ZANTHOXYLUM AMERICANUM BARK	1 (3.3)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	1 (3.3)
ORGANIC NITRATES	
GLYCERYL TRINITRATE	1 (3.3) 1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoc' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoc

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
OSMOTICALLY ACTING LAXATIVES	8 (26.7)
MACROGOL	4 (13.3)
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	4 (13.3)
LACTULOSE	1 (3.3)
OTHER ANALGESICS AND ANTIPYRETICS	8 (26.7)
PREGABALIN	6 (20.0)
AMITRIPTYLINE	1 (3.3)
AMITRIPTYLINE HYDROCHLORIDE	1 (3.3)
GABAPENTIN	1 (3.3)
OTHER ANTIDEPRESSANTS	2 (6.7)
MIRTAZAPINE	2 (6.7)
OTHER ANTIDIARRHEALS	1 (3.3)
COLESTYRAMINE	1 (3.3)
OTHER BLOOD PRODUCTS	5 (16.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHODrug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-med.sas

Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoc (N=30) n (%)
OTHER BLOOD PRODUCTS (Continued)	
RED BLOOD CELLS, CONCENTRATED	4 (13.3)
PLATELETS	2 (6.7)
RED BLOOD CELLS	2 (6.7)
PLATELETS, CONCENTRATED	1 (3.3)
OTHER COMBINATIONS OF NUTRIENTS	
CAFFEINE;CARBOHYDRATES NOS;FATS NOS;FIBRE, DIETARY;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1 (3.3) 1 (3.3)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	
DENOSUMAB	15 (50.0) 15 (50.0)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	
SIMETICONE	2 (6.7) 2 (6.7)
OTHER HORMONE ANTAGONISTS AND RELATED AGENTS	
ABIRATERONE	2 (6.7) 1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoc' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHODrug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoc

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
OTHER HORMONE ANTAGONISTS AND RELATED AGENTS (Continued)	
ABIRATERONE ACETATE	1 (3.3)
OTHER IMMUNOSUPPRESSANTS	1 (3.3)
METHOTREXATE	1 (3.3)
OTHER LIPID MODIFYING AGENTS	1 (3.3)
EZETIMIBE	1 (3.3)
OTHER MINERAL PRODUCTS	1 (3.3)
MANGANESE	1 (3.3)
OTHER OPIOIDS	4 (13.3)
NALOXONE HYDROCHLORIDE; TILIDINE HYDROCHLORIDE	1 (3.3)
TAPENTADOL HYDROCHLORIDE	1 (3.3)
TRAMADOL	1 (3.3)
TRAMADOL HYDROCHLORIDE	1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
OTHER VIRAL VACCINES	10 (33.3)
TOZINAMERAN	6 (20.0)
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	3 (10.0)
COVID-19 VACCINE mRNA (MRNA 1273)	1 (3.3)
PERIPHERAL OPIOID RECEPTOR ANTAGONISTS	1 (3.3)
METHYLNALTREXONE BROMIDE	1 (3.3)
PHENYLPIPERIDINE DERIVATIVES	3 (10.0)
FENTANYL	2 (6.7)
PETHIDINE HYDROCHLORIDE	1 (3.3)
PIPERAZINE DERIVATIVES	1 (3.3)
CETIRIZINE HYDROCHLORIDE	1 (3.3)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	8 (26.7)
ACETYLSALICYLIC ACID	6 (20.0)
CLOPIDOGREL	1 (3.3)
DIPYRIDAMOLE	1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO DRUG Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoc (N=30) n (%)
POTASSIUM POTASSIUM CHLORIDE	1 (3.3) 1 (3.3)
PREPARATIONS INHIBITING URIC ACID PRODUCTION ALLOPURINOL	3 (10.0) 3 (10.0)
PROPIONIC ACID DERIVATIVES IBUPROFEN	10 (33.3) 10 (33.3)
PROPELLERS METOCLOPRAMIDE	7 (23.3) 7 (23.3)
PROTON PUMP INHIBITORS PANTOPRAZOLE ESOMEPRAZOLE PANTOPRAZOLE SODIUM SESQUIHYDRATE	14 (46.7) 10 (33.3) 2 (6.7) 2 (6.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoc' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHODrug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoc

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
PYRAZOLONES	18 (60.0)
METAMIZOLE SODIUM	16 (53.3)
METAMIZOLE	4 (13.3)
PYRIMIDINE ANALOGUES	1 (3.3)
CAPECITABINE	1 (3.3)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	2 (6.7)
ESCITALOPRAM	1 (3.3)
SERTRALINE	1 (3.3)
SELENIUM	1 (3.3)
SELENIUM	1 (3.3)
SEROTONIN (5HT3) ANTAGONISTS	20 (66.7)
ONDANSETRON	17 (56.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHODrug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
SEROTONIN (5HT3) ANTAGONISTS (Continued) GRANisetron	5 (16.7)
SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS EMPAGLIFLOZIN	2 (6.7) 2 (6.7)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAhydrate;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAhydrate;MALIC ACID;POTASSIUM CHLORIDE;SODIUM ACETATE TRIhydrate;SODIUM CHLORIDE ELECTROLYTES NOS	14 (46.7) 10 (33.3) 5 (16.7) 1 (3.3)
SUBSTITUTED ALKYLAMINES DIMETINDENE MALEATE	1 (3.3) 1 (3.3)
SULFONAMIDES, PLAIN TORASEMIDE	7 (23.3) 5 (16.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHODrug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
SULFONAMIDES, PLAIN (Continued) FUROSEMIDE	3 (10.0)
THIAZIDES, PLAIN HYDROCHLOROTHIAZIDE	2 (6.7) 2 (6.7)
THIRD-GENERATION CEPHALOSPORINS CEFPODOXIME	1 (3.3) 1 (3.3)
THYROID HORMONES LEVOTHYROXINE SODIUM	2 (6.7) 2 (6.7)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS BIOTIN;BROMELAINS;LECITHIN;PAPAIN;SODIUM SELENITE COFFEE COAL;COMMIPHORA MYRRHA;MATRICARIA RECUTITA THIOCTIC ACID	1 (3.3) 1 (3.3) 1 (3.3) 1 (3.3)
VARIOUS DIAGNOSTIC RADIOPHARMACEUTICALS	1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO DRUG Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-7s Concomitant medications during study treatment (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoc (N=30) n (%)
VARIOUS DIAGNOSTIC RADIOPHARMACEUTICALS (Continued)	
VARIOUS DIAGNOSTIC RADIOPHARMACEUTICALS	1 (3.3)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	2 (6.7)
CYANOCOBALAMIN	1 (3.3)
CYANOCOBALAMIN;FOLIC ACID;URIDINE TRIPHOSPHATE SODIUM	1 (3.3)
VITAMIN D AND ANALOGUES	5 (16.7)
COLECALCIFEROL	4 (13.3)
VITAMIN D NOS	1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoc' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications are all medications starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoc

Output ID: T-1-3-7s 2021-09-22 17:00

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-8 Concurrent radiotherapy (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Number of patients with at least one concurrent radiotherapy, n (%)	93 (17.6)	41 (20.0)	134 (18.3)
Number of concurrent radiotherapies	131	57	188
Site of radiotherapy, n (%)			
Back	33 (6.2)	15 (7.3)	48 (6.5)
Other	12 (2.3)	4 (2.0)	16 (2.2)
Pelvic bone	10 (1.9)	5 (2.4)	15 (2.0)
Femur	9 (1.7)	0	9 (1.2)
Vertebral column	9 (1.7)	9 (4.4)	18 (2.5)
Bone	6 (1.1)	2 (1.0)	8 (1.1)
Hip	6 (1.1)	2 (1.0)	8 (1.1)
Rib	6 (1.1)	2 (1.0)	8 (1.1)
Iliac crest	5 (0.9)	0	5 (0.7)
Prostate gland	5 (0.9)	3 (1.5)	8 (1.1)
Sacrum	5 (0.9)	2 (1.0)	7 (1.0)
Brain	3 (0.6)	0	3 (0.4)
Lower extremity bone	3 (0.6)	0	3 (0.4)
Scapula	3 (0.6)	2 (1.0)	5 (0.7)
Skull	2 (0.4)	2 (1.0)	4 (0.5)
Lung	1 (0.2)	0	1 (0.1)
Rectum	1 (0.2)	0	1 (0.1)
Supraclavicular lymph node	1 (0.2)	0	1 (0.1)
Lymph node	0	1 (0.5)	1 (0.1)
Neck	0	1 (0.5)	1 (0.1)

Site of radiotherapy are sorted in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each site of radiotherapy.

Concurrent radiotherapy are all radiotherapies starting on or after the start of randomized treatment or starting prior to and continuing after start of randomized treatment but not more than 30 days after end of randomized treatment.

Output ID: T-1-3-8 2021-09-22 16:46

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-8s Concurrent radiotherapy (Sub-study safety analysis set)

Final Version

No data to report

Site of radiotherapy are sorted in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each site of radiotherapy.

Concurrent radiotherapy are all radiotherapies starting on or after the start of study treatment or starting prior to and continuing after start of study treatment but not more than 30 days after end of study treatment.

Output ID: T-1-3-8s 2021-09-22 16:46

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9 Concurrent surgical and therapeutic procedures (FAS safety set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Number of patients with at least one concurrent surgical and/or therapeutic procedure	123 (23.3)	40 (19.5)	163 (22.2)
Investigations			
Chest X-ray	59 (11.2)	29 (14.1)	88 (12.0)
Computerised tomogram	8 (1.5)	5 (2.4)	13 (1.8)
Cystoscopy	8 (1.5)	1 (0.5)	9 (1.2)
Biopsy liver	7 (1.3)	1 (0.5)	8 (1.1)
Electrocardiogram	6 (1.1)	0	6 (0.8)
Magnetic resonance imaging	4 (0.8)	1 (0.5)	5 (0.7)
Magnetic resonance imaging spinal	4 (0.8)	3 (1.5)	7 (1.0)
Aspiration pleural cavity	4 (0.8)	4 (2.0)	8 (1.1)
Biopsy lymph gland	3 (0.6)	2 (1.0)	5 (0.7)
Biopsy skin	3 (0.6)	1 (0.5)	4 (0.5)
Computerised tomogram head	3 (0.6)	4 (2.0)	7 (1.0)
Computerised tomogram spine	3 (0.6)	0	3 (0.4)
Computerised tomogram thorax	3 (0.6)	2 (1.0)	5 (0.7)
Ultrasound Doppler	3 (0.6)	2 (1.0)	5 (0.7)
Ultrasound scan	3 (0.6)	4 (2.0)	7 (1.0)
Biopsy	2 (0.4)	1 (0.5)	3 (0.4)
Biopsy bone marrow	2 (0.4)	0	2 (0.3)
Colonoscopy	2 (0.4)	1 (0.5)	3 (0.4)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of randomized treatment or starting prior to and continuing after randomized treatment but not more than 30 days after end of randomized treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9 Concurrent surgical and therapeutic procedures (FAS safety set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Investigations (Continued)			
Computerised tomogram abdomen	2 (0.4)	0	2 (0.3)
Computerised tomogram pelvis	2 (0.4)	0	2 (0.3)
Echocardiogram	2 (0.4)	2 (1.0)	4 (0.5)
Magnetic resonance imaging abdominal	2 (0.4)	0	2 (0.3)
Magnetic resonance imaging head	2 (0.4)	1 (0.5)	3 (0.4)
Paracentesis	2 (0.4)	0	2 (0.3)
Ultrasound abdomen	2 (0.4)	1 (0.5)	3 (0.4)
Abdominal X-ray	1 (0.2)	2 (1.0)	3 (0.4)
Angiogram	1 (0.2)	0	1 (0.1)
Arthrogram	1 (0.2)	0	1 (0.1)
Bacterial test	1 (0.2)	2 (1.0)	3 (0.4)
Biopsy kidney	1 (0.2)	0	1 (0.1)
Bone scan	1 (0.2)	1 (0.5)	2 (0.3)
Catheterisation cardiac	1 (0.2)	0	1 (0.1)
Device function test	1 (0.2)	0	1 (0.1)
Diagnostic aspiration	1 (0.2)	0	1 (0.1)
Endoscopy upper gastrointestinal tract	1 (0.2)	1 (0.5)	2 (0.3)
Fundoscopy	1 (0.2)	0	1 (0.1)
Gastrointestinal tract biopsy	1 (0.2)	0	1 (0.1)
Gene mutation identification test	1 (0.2)	1 (0.5)	2 (0.3)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of randomized treatment or starting prior to and continuing after randomized treatment but not more than 30 days after end of randomized treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9 Concurrent surgical and therapeutic procedures (FAS safety set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Investigations (Continued)			
Magnetic resonance imaging neck	1 (0.2)	0	1 (0.1)
Magnetic resonance imaging thoracic	1 (0.2)	0	1 (0.1)
Oesophagogastroduodenoscopy	1 (0.2)	0	1 (0.1)
Ophthalmological examination	1 (0.2)	0	1 (0.1)
Positron emission tomogram	1 (0.2)	0	1 (0.1)
Renal scan	1 (0.2)	1 (0.5)	2 (0.3)
Spinal myelogram	1 (0.2)	1 (0.5)	2 (0.3)
Ultrasound thyroid	1 (0.2)	0	1 (0.1)
Viral test	1 (0.2)	0	1 (0.1)
X-ray dental	1 (0.2)	0	1 (0.1)
BRCA1 gene mutation assay	0	1 (0.5)	1 (0.1)
Biopsy bone	0	3 (1.5)	3 (0.4)
Biopsy tongue	0	1 (0.5)	1 (0.1)
Bronchoalveolar lavage	0	1 (0.5)	1 (0.1)
Bronchoscopy	0	1 (0.5)	1 (0.1)
Lumbar puncture	0	1 (0.5)	1 (0.1)
Magnetic resonance imaging whole body	0	1 (0.5)	1 (0.1)
Mycobacterium tuberculosis complex test	0	1 (0.5)	1 (0.1)
Spinal X-ray	0	1 (0.5)	1 (0.1)
Sputum test	0	1 (0.5)	1 (0.1)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of randomized treatment or starting prior to and continuing after randomized treatment but not more than 30 days after end of randomized treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9 Concurrent surgical and therapeutic procedures (FAS safety set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Investigations (Continued)			
Ultrasound kidney	0	1 (0.5)	1 (0.1)
Ventilation/perfusion scan	0	1 (0.5)	1 (0.1)
X-ray	0	1 (0.5)	1 (0.1)
X-ray limb	0	2 (1.0)	2 (0.3)
X-ray of pelvis and hip	0	1 (0.5)	1 (0.1)
Surgical and medical procedures			
Nephrostomy	89 (16.8)	21 (10.2)	110 (15.0)
Ureteral stent insertion	12 (2.3)	2 (1.0)	14 (1.9)
Cataract operation	10 (1.9)	4 (2.0)	14 (1.9)
Bladder catheterisation	7 (1.3)	0	7 (1.0)
Cryotherapy	4 (0.8)	0	4 (0.5)
Tooth extraction	4 (0.8)	2 (1.0)	6 (0.8)
Vertebraloplasty	4 (0.8)	1 (0.5)	5 (0.7)
Spinal laminectomy	3 (0.6)	1 (0.5)	4 (0.5)
Stent placement	3 (0.6)	0	3 (0.4)
Ureteral stent removal	3 (0.6)	0	3 (0.4)
Bladder operation	2 (0.4)	0	2 (0.3)
Endodontic procedure	2 (0.4)	0	2 (0.3)
Epidural injection	2 (0.4)	0	2 (0.3)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of randomized treatment or starting prior to and continuing after randomized treatment but not more than 30 days after end of randomized treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9 Concurrent surgical and therapeutic procedures (FAS safety set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Surgical and medical procedures (Continued)			
Knee arthroplasty	2 (0.4)	0	2 (0.3)
Micrographic skin surgery	2 (0.4)	0	2 (0.3)
Peripheral nerve neurostimulation	2 (0.4)	0	2 (0.3)
Spinal decompression	2 (0.4)	0	2 (0.3)
Spinal fusion surgery	2 (0.4)	2 (1.0)	4 (0.5)
Transurethral prostatectomy	2 (0.4)	1 (0.5)	3 (0.4)
Tumour excision	2 (0.4)	0	2 (0.3)
Abdominal cavity drainage	1 (0.2)	0	1 (0.1)
Appendectomy	1 (0.2)	0	1 (0.1)
Artificial urinary sphincter implant	1 (0.2)	0	1 (0.1)
Biliary catheter insertion	1 (0.2)	0	1 (0.1)
Bladder irrigation	1 (0.2)	0	1 (0.1)
Blepharoplasty	1 (0.2)	0	1 (0.1)
Cancer surgery	1 (0.2)	0	1 (0.1)
Cardiac pacemaker insertion	1 (0.2)	0	1 (0.1)
Circumcision	1 (0.2)	0	1 (0.1)
Colectomy	1 (0.2)	2 (1.0)	3 (0.4)
Coronary artery bypass	1 (0.2)	0	1 (0.1)
Eye laser surgery	1 (0.2)	0	1 (0.1)
Fracture treatment	1 (0.2)	0	1 (0.1)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of randomized treatment or starting prior to and continuing after randomized treatment but not more than 30 days after end of randomized treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9 Concurrent surgical and therapeutic procedures (FAS safety set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Surgical and medical procedures (Continued)			
Gastrointestinal tube insertion	1 (0.2)	0	1 (0.1)
Hernia repair	1 (0.2)	0	1 (0.1)
High frequency ablation	1 (0.2)	1 (0.5)	2 (0.3)
Implantable defibrillator insertion	1 (0.2)	0	1 (0.1)
Internal fixation of fracture	1 (0.2)	0	1 (0.1)
Intervertebral disc operation	1 (0.2)	0	1 (0.1)
Intramedullary rod insertion	1 (0.2)	0	1 (0.1)
Intraocular lens implant	1 (0.2)	0	1 (0.1)
Joint injection	1 (0.2)	1 (0.5)	2 (0.3)
Limb immobilisation	1 (0.2)	0	1 (0.1)
Liver ablation	1 (0.2)	0	1 (0.1)
Nasal cavity packing	1 (0.2)	0	1 (0.1)
Open reduction of fracture	1 (0.2)	0	1 (0.1)
Penile operation	1 (0.2)	0	1 (0.1)
Peripheral artery bypass	1 (0.2)	0	1 (0.1)
Peripheral nerve decompression	1 (0.2)	0	1 (0.1)
Physiotherapy	1 (0.2)	0	1 (0.1)
Prostatic operation	1 (0.2)	0	1 (0.1)
Renal stone removal	1 (0.2)	0	1 (0.1)
Skin lesion removal	1 (0.2)	0	1 (0.1)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of randomized treatment or starting prior to and continuing after randomized treatment but not more than 30 days after end of randomized treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9 Concurrent surgical and therapeutic procedures (FAS safety set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Surgical and medical procedures (Continued)			
Skin neoplasm excision	1 (0.2)	1 (0.5)	2 (0.3)
Skin operation	1 (0.2)	0	1 (0.1)
Spinal support	1 (0.2)	0	1 (0.1)
Thoracic cavity drainage	1 (0.2)	1 (0.5)	2 (0.3)
Transcatheter aortic valve implantation	1 (0.2)	0	1 (0.1)
Transurethral bladder resection	1 (0.2)	0	1 (0.1)
Ureteropyelostomy	1 (0.2)	0	1 (0.1)
Urethral dilation procedure	1 (0.2)	0	1 (0.1)
Urethral stent insertion	1 (0.2)	1 (0.5)	2 (0.3)
Vena cava filter insertion	1 (0.2)	0	1 (0.1)
Wound treatment	1 (0.2)	0	1 (0.1)
Adhesiolysis	0	1 (0.5)	1 (0.1)
Coronary angioplasty	0	1 (0.5)	1 (0.1)
Coronary arterial stent insertion	0	1 (0.5)	1 (0.1)
Ear meatoplasty	0	1 (0.5)	1 (0.1)
Glossectomy	0	1 (0.5)	1 (0.1)
Nerve block	0	1 (0.5)	1 (0.1)
Skin graft	0	1 (0.5)	1 (0.1)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of randomized treatment or starting prior to and continuing after randomized treatment but not more than 30 days after end of randomized treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9s Concurrent surgical and therapeutic procedures (Sub-study safety analysis set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Number of patients with at least one concurrent surgical and/or therapeutic procedure	12 (40.0)
Investigations	11 (36.7)
Renal scan	7 (23.3)
Salivary scan	6 (20.0)
Echocardiogram	4 (13.3)
Ultrasound scan	3 (10.0)
Aspiration pleural cavity	2 (6.7)
Computerised tomogram thorax	2 (6.7)
Magnetic resonance imaging	2 (6.7)
Ultrasound Doppler	2 (6.7)
Ultrasound kidney	2 (6.7)
Biopsy bone	1 (3.3)
Catheterisation cardiac	1 (3.3)
Computerised tomogram spine	1 (3.3)
Cystometrogram	1 (3.3)
Electrocardiogram	1 (3.3)
Endoscopy upper gastrointestinal tract	1 (3.3)
Magnetic resonance imaging spinal	1 (3.3)
Plethysmography	1 (3.3)
Positron emission tomogram	1 (3.3)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of study treatment or starting prior to and continuing after study treatment but not more than 30 days after end of study treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9s 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9s Concurrent surgical and therapeutic procedures (Sub-study safety analysis set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Investigations (Continued)	
Spinal X-ray	1 (3.3)
Ultrasound abdomen	1 (3.3)
Ultrasound chest	1 (3.3)
X-ray	1 (3.3)
X-ray limb	1 (3.3)
Surgical and medical procedures	5 (16.7)
Ureteral stent insertion	2 (6.7)
Alveoplasty	1 (3.3)
Bladder catheter permanent	1 (3.3)
Bladder catheterisation	1 (3.3)
Catheter removal	1 (3.3)
Central venous catheterisation	1 (3.3)
Jaw operation	1 (3.3)
Maxillary antrum operation	1 (3.3)
Nail operation	1 (3.3)
Sequestrectomy	1 (3.3)
Spinal laminectomy	1 (3.3)
Thoracic cavity drainage	1 (3.3)
Tooth extraction	1 (3.3)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of study treatment or starting prior to and continuing after study treatment but not more than 30 days after end of study treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9s 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 1-3-9s Concurrent surgical and therapeutic procedures (Sub-study safety analysis set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Surgical and medical procedures (Continued)	
Transurethral bladder resection	1 (3.3)
Transurethral incision of prostate	1 (3.3)
Urethral meatotomy	1 (3.3)
Wound treatment	1 (3.3)

Every patient is counted a single time for each applicable category.

Concurrent procedures (including diagnostic procedures) are all procedures starting on or after the start of study treatment or starting prior to and continuing after study treatment but not more than 30 days after end of study treatment.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0.

Output ID: T-1-3-9s 2021-09-22 17:03

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Number of patients with at least one concomitant medication indicated as study BSC/BSoC	529 (100)	205 (100)	734 (100)
3-OXOANDROSTEN (4) DERIVATIVES TESTOSTERONE CIPIONATE	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	18 (3.4)	10 (4.9)	28 (3.8)
DICLOFENAC SODIUM	8 (1.5)	3 (1.5)	11 (1.5)
DICLOFENAC	7 (1.3)	3 (1.5)	10 (1.4)
INDOMETACIN	2 (0.4)	1 (0.5)	3 (0.4)
KETOROLAC	1 (0.2)	0	1 (0.1)
DICLOFENAC;MISOPROSTOL	0	1 (0.5)	1 (0.1)
ETODOLAC	0	1 (0.5)	1 (0.1)
KETOROLAC TROMETHAMINE	0	1 (0.5)	1 (0.1)
ALPHA-ADRENORECEPTOR ANTAGONISTS	74 (14.0)	41 (20.0)	115 (15.7)
TAMSULOSIN	36 (6.8)	15 (7.3)	51 (6.9)
TAMSULOSIN HYDROCHLORIDE	33 (6.2)	16 (7.8)	49 (6.7)
ALFUZOSIN	3 (0.6)	1 (0.5)	4 (0.5)
DOXAZOSIN	2 (0.4)	1 (0.5)	3 (0.4)
SILODOSIN	2 (0.4)	4 (2.0)	6 (0.8)
ALFUZOSIN HYDROCHLORIDE	1 (0.2)	3 (1.5)	4 (0.5)
TERAZOSIN	1 (0.2)	2 (1.0)	3 (0.4)
DOXAZOSIN MESILATE	0	1 (0.5)	1 (0.1)
SOLIFENACIN;TAMSULOSIN	0	1 (0.5)	1 (0.1)
AMINO ACIDS	2 (0.4)	0	2 (0.3)
TRANEXAMIC ACID	2 (0.4)	0	2 (0.3)
ANILIDES	214 (40.5)	92 (44.9)	306 (41.7)
PARACETAMOL	202 (38.2)	88 (42.9)	290 (39.5)
DIPHENHYDRAMINE	6 (1.1)	1 (0.5)	7 (1.0)
HYDROCHLORIDE;PARACETAMOL ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (0.4)	3 (1.5)	5 (0.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications indicated as BSC/BSoC are all medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHODrug Global version Mar 2021 B3.

Output ID: T-1-3-10 2021-09-22 16:45

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ANILIDES (Continued)			
ACETYLSALICYLIC ACID;ALUMINIUM HYDROXIDE GEL, DRIED;CAFFEINE;MAGNESIUM HYDROXIDE;PARACETAMOL	1 (0.2)	0	1 (0.1)
BUTALBITAL;CAFFEINE;PARACETAMOL	1 (0.2)	1 (0.5)	2 (0.3)
CHLORPHENAMINE MALEATE;PARACETAMOL	1 (0.2)	0	1 (0.1)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
DIPHENHYDRAMINE;PARACETAMOL	0	2 (1.0)	2 (0.3)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL	0	1 (0.5)	1 (0.1)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	182 (34.4)	98 (47.8)	280 (38.1)
ANTI-ANDROGENS	157 (29.7)	88 (42.9)	245 (33.4)
ENZALUTAMIDE	16 (3.0)	10 (4.9)	26 (3.5)
BICALUTAMIDE	10 (1.9)	1 (0.5)	11 (1.5)
APALUTAMIDE	2 (0.4)	1 (0.5)	3 (0.4)
DAROLUTAMIDE	1 (0.2)	0	1 (0.1)
NILUTAMIDE	2 (0.4)	2 (1.0)	4 (0.5)
CYPROTERONE	2 (0.4)	0	2 (0.3)
CYPROTERONE ACETATE	0	2 (1.0)	2 (0.3)
ANTICORTICOSTEROIDS	2 (0.4)	5 (2.4)	7 (1.0)
KETOCONAZOLE	2 (0.4)	5 (2.4)	7 (1.0)
ANTIPROPULSIVES	42 (7.9)	11 (5.4)	53 (7.2)
LOPERAMIDE HYDROCHLORIDE	28 (5.3)	7 (3.4)	35 (4.8)
LOPERAMIDE	15 (2.8)	4 (2.0)	19 (2.6)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications indicated as BSC/BSoC are all medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHODrug Global version Mar 2021 B3.

Output ID: T-1-3-10 2021-09-22 16:45

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
BISMUTH PREPARATIONS	3 (0.6)	1 (0.5)	4 (0.5)
BISMUTH SUBSALICYLATE	3 (0.6)	1 (0.5)	4 (0.5)
BISPHOSPHONATES	45 (8.5)	28 (13.7)	73 (9.9)
ZOLEDRONIC ACID MONOHYDRATE	19 (3.6)	15 (7.3)	34 (4.6)
ZOLEDRONIC ACID	18 (3.4)	8 (3.9)	26 (3.5)
ALENDRONATE SODIUM	4 (0.8)	4 (2.0)	8 (1.1)
ALENDRONIC ACID	2 (0.4)	2 (1.0)	4 (0.5)
RISEDRONATE SODIUM	2 (0.4)	0	2 (0.3)
BISPHOSPHONATES, COMBINATIONS	1 (0.2)	1 (0.5)	2 (0.3)
CALCIUM CARBONATE;RISEDRONATE SODIUM	1 (0.2)	0	1 (0.1)
ALENDRONATE SODIUM;VITAMIN D NOS	0	1 (0.5)	1 (0.1)
BLOOD COAGULATION FACTORS	1 (0.2)	0	1 (0.1)
FACTOR I (FIBRINOGEN);FACTOR VIII (ANTIHAEMOPHILIC FACTOR);FACTOR XIII (FIBRIN STABILISING FACTOR);VON WILLEBRAND FACTOR	1 (0.2)	0	1 (0.1)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS	4 (0.8)	2 (1.0)	6 (0.8)
ALBUMIN HUMAN	4 (0.8)	2 (1.0)	6 (0.8)
CALCITONIN PREPARATIONS	1 (0.2)	0	1 (0.1)
CALCITONIN, SALMON	1 (0.2)	0	1 (0.1)
COLONY STIMULATING FACTORS	11 (2.1)	3 (1.5)	14 (1.9)
FILGRASTIM	5 (0.9)	0	5 (0.7)
PEGFILGRASTIM	5 (0.9)	3 (1.5)	8 (1.1)
FILGRASTIM SNDZ	2 (0.4)	0	2 (0.3)
LENOGRASTIM	1 (0.2)	0	1 (0.1)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications indicated as BSC/BSoC are all medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-10 2021-09-22 16:45

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
CORTICOSTEROIDS ACTING LOCALLY BUDESONIDE	1 (0.2) 1 (0.2)	0 0	1 (0.1) 1 (0.1)
COXIBS CELECOXIB ETORICOXIB	11 (2.1) 10 (1.9) 1 (0.2)	7 (3.4) 7 (3.4) 0	18 (2.5) 17 (2.3) 1 (0.1)
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES OLANZAPINE	11 (2.1) 11 (2.1)	6 (2.9) 6 (2.9)	17 (2.3) 17 (2.3)
DIPHENYLPROPYLAMINE DERIVATIVES METHADONE METHADONE HYDROCHLORIDE	13 (2.5) 13 (2.5) 0	3 (1.5) 2 (1.0) 1 (0.5)	16 (2.2) 15 (2.0) 1 (0.1)
ELECTROLYTE SOLUTIONS SODIUM CHLORIDE MAGNESIUM SULFATE POTASSIUM CHLORIDE CALCIUM GLUCONATE POTASSIUM PHOSPHATE DIBASIC SODIUM BICARBONATE SODIUM PHOSPHATE CALCIUM CHLORIDE POTASSIUM ACETATE	66 (12.5) 60 (11.3) 6 (1.1) 5 (0.9) 2 (0.4) 2 (0.4) 2 (0.4) 2 (0.4) 1 (0.2) 1 (0.2)	12 (5.9) 9 (4.4) 0 1 (0.5) 2 (1.0) 0 1 (0.5) 0 0	78 (10.6) 69 (9.4) 6 (0.8) 6 (0.8) 4 (0.5) 2 (0.3) 3 (0.4) 2 (0.3) 1 (0.1) 1 (0.1)
ESTROGENS ESTRADIOL DIETHYLSТИLBESTROL	12 (2.3) 10 (1.9) 3 (0.6)	1 (0.5) 0 1 (0.5)	13 (1.8) 10 (1.4) 4 (0.5)
GLUCOCORTICOIDS PREDNISONE DEXAMETHASONE PREDNISOLONE HYDROCORTISONE	337 (63.7) 182 (34.4) 162 (30.6) 43 (8.1) 11 (2.1)	134 (65.4) 77 (37.6) 35 (17.1) 24 (11.7) 6 (2.9)	471 (64.2) 259 (35.3) 197 (26.8) 67 (9.1) 17 (2.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

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Coded using WHODrug Global version Mar 2021 B3.

Output ID: T-1-3-10 2021-09-22 16:45

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
GLUCOCORTICOIDS (Continued)			
METHYLPREDNISOLONE	8 (1.5)	5 (2.4)	13 (1.8)
CORTISONE	4 (0.8)	1 (0.5)	5 (0.7)
BETAMETHASONE SODIUM PHOSPHATE	3 (0.6)	2 (1.0)	5 (0.7)
TRIAMCINOLONE ACTONIDE	3 (0.6)	1 (0.5)	4 (0.5)
METHYLPREDNISOLONE SODIUM SUCCINATE	2 (0.4)	0	2 (0.3)
TRIAMCINOLONE	2 (0.4)	0	2 (0.3)
DEXAMETHASONE SODIUM SUCCINATE	1 (0.2)	0	1 (0.1)
DEXAMETHASONE ACETATE	0	1 (0.5)	1 (0.1)
METHYLPREDNISOLONE ACETATE	0	1 (0.5)	1 (0.1)
GONADOTROPIN RELEASING HORMONE ANALOGUES			
LEUPRORELIN ACETATE	468 (88.5)	172 (83.9)	640 (87.2)
LEUPRORELIN	309 (58.4)	96 (46.8)	405 (55.2)
GOSERELIN ACETATE	74 (14.0)	33 (16.1)	107 (14.6)
GOSERELIN	34 (6.4)	16 (7.8)	50 (6.8)
TRIPTORELIN ACETATE	20 (3.8)	8 (3.9)	28 (3.8)
TRIPTORELIN EMBONATE	19 (3.6)	10 (4.9)	29 (4.0)
TRIPTORELIN	14 (2.6)	7 (3.4)	21 (2.9)
BUSERELIN ACETATE	7 (1.3)	3 (1.5)	10 (1.4)
	0	1 (0.5)	1 (0.1)
HERBAL DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY			
SERENOA REPENS EXTRACT	1 (0.2)	0	1 (0.1)
IRON BIVALENT, ORAL PREPARATIONS			
FERREROUS SULFATE	29 (5.5)	21 (10.2)	50 (6.8)
IRON	19 (3.6)	12 (5.9)	31 (4.2)
ASCORBIC ACID;IRON	8 (1.5)	6 (2.9)	14 (1.9)
FERREROUS GLUCONATE	1 (0.2)	0	1 (0.1)
FERREROUS FUMARATE	1 (0.2)	1 (0.5)	2 (0.3)
IRON POLYSACCHARIDE COMPLEX	0	1 (0.5)	1 (0.1)
IRON IN COMBINATION WITH FOLIC ACID	0	1 (0.5)	1 (0.1)

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Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
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IRON IN COMBINATION WITH FOLIC ACID (Continued)			
FOLIC ACID;IRON PIDOLATE	1 (0.2)	0	1 (0.1)
IRON IN OTHER COMBINATIONS	1 (0.2)	0	1 (0.1)
FERROUS GLUCONATE;HERBAL NOS;VITAMINS NOS	1 (0.2)	0	1 (0.1)
IRON TRIVALENT, ORAL PREPARATIONS	2 (0.4)	0	2 (0.3)
IRON	2 (0.4)	0	2 (0.3)
IRON, PARENTERAL PREPARATIONS	2 (0.4)	3 (1.5)	5 (0.7)
FERRIC CARBOXYMALTPOSE	1 (0.2)	2 (1.0)	3 (0.4)
IRON	1 (0.2)	0	1 (0.1)
SACCHARATED IRON OXIDE	0	1 (0.5)	1 (0.1)
MEDICAL GASES	6 (1.1)	2 (1.0)	8 (1.1)
OXYGEN	6 (1.1)	2 (1.0)	8 (1.1)
MORPHINAN DERIVATIVES	1 (0.2)	0	1 (0.1)
LEVORPHANOL	1 (0.2)	0	1 (0.1)
NATURAL OPIUM ALKALOIDS	178 (33.6)	76 (37.1)	254 (34.6)
OXYCODONE	64 (12.1)	20 (9.8)	84 (11.4)
OXYCODONE HYDROCHLORIDE	62 (11.7)	24 (11.7)	86 (11.7)
MORPHINE	37 (7.0)	19 (9.3)	56 (7.6)
HYDROMORPHONE	24 (4.5)	7 (3.4)	31 (4.2)
MORPHINE SULFATE	22 (4.2)	17 (8.3)	39 (5.3)
HYDROMORPHONE HYDROCHLORIDE	20 (3.8)	5 (2.4)	25 (3.4)
HYDROCODONE	9 (1.7)	5 (2.4)	14 (1.9)
MORPHINE SULFATE PENTAHYDRATE	4 (0.8)	3 (1.5)	7 (1.0)
CODEINE	1 (0.2)	1 (0.5)	2 (0.3)
NALOXONE HYDROCHLORIDE;OXYCODONE	1 (0.2)	0	1 (0.1)
HYDROCHLORIDE			
OXYMORPHONE	1 (0.2)	0	1 (0.1)
MORPHINE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)

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Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
NOT CODED	23 (4.3)	3 (1.5)	26 (3.5)
MEGESTROL	11 (2.1)	3 (1.5)	14 (1.9)
MEGESTROL ACETATE	10 (1.9)	0	10 (1.4)
CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN	2 (0.4)	0	2 (0.3)
CYPROHEPTADINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
OPPIOIDS IN COMBINATION WITH NON-OPPIOID ANALGESICS	95 (18.0)	40 (19.5)	135 (18.4)
HYDROCODONE BITARTRATE;PARACETAMOL	30 (5.7)	14 (6.8)	44 (6.0)
HYDROCODONE;PARACETAMOL	29 (5.5)	10 (4.9)	39 (5.3)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	21 (4.0)	8 (3.9)	29 (4.0)
CODEINE PHOSPHATE;PARACETAMOL	10 (1.9)	4 (2.0)	14 (1.9)
CODEINE;PARACETAMOL	6 (1.1)	0	6 (0.8)
OXYCODONE HYDROCHLORIDE;OXYCODONE	5 (0.9)	2 (1.0)	7 (1.0)
TEREPHTHALATE;PARACETAMOL			
PAPAVER SOMNIFERUM;PARACETAMOL	2 (0.4)	2 (1.0)	4 (0.5)
PARACETAMOL;TRAMADOL HYDROCHLORIDE	2 (0.4)	2 (1.0)	4 (0.5)
DIHYDROCODEINE;PARACETAMOL	1 (0.2)	0	1 (0.1)
CAFFEINE;PAPAVER SOMNIFERUM	0	1 (0.5)	1 (0.1)
LATEX;PARACETAMOL			
CODEINE PHOSPHATE;DOXYLAMINE	0	1 (0.5)	1 (0.1)
SUCCINATE;PARACETAMOL			
OXYCODONE;PARACETAMOL	0	1 (0.5)	1 (0.1)
ORIPAVINE DERIVATIVES	2 (0.4)	0	2 (0.3)
BUPRENORPHINE	2 (0.4)	0	2 (0.3)
OTHER ANALGESICS AND ANTIPYRETICS	28 (5.3)	21 (10.2)	49 (6.7)
PREGABALIN	23 (4.3)	19 (9.3)	42 (5.7)
AMITRIPTYLINE	2 (0.4)	3 (1.5)	5 (0.7)
NEFOPAM HYDROCHLORIDE	2 (0.4)	1 (0.5)	3 (0.4)
AMITRIPTYLINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
NEFOPAM	1 (0.2)	0	1 (0.1)

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Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER ANALGESICS AND ANTIPYRETICS (Continued)			
OTHER ANALGESICS AND ANTIPYRETICS	1 (0.2)	0	1 (0.1)
CARBAMAZEPINE	0	1 (0.5)	1 (0.1)
OTHER ANTI-PARATHYROID AGENTS	1 (0.2)	0	1 (0.1)
CINACALCET	1 (0.2)	0	1 (0.1)
OTHER ANTIANEMIC PREPARATIONS	15 (2.8)	3 (1.5)	18 (2.5)
EPOETIN ALFA	6 (1.1)	2 (1.0)	8 (1.1)
DARBEOPOETIN ALFA	5 (0.9)	1 (0.5)	6 (0.8)
EPOETIN ZETA	2 (0.4)	1 (0.5)	3 (0.4)
EPOETIN ALFA EPBX	1 (0.2)	0	1 (0.1)
ROXADUSTAT	1 (0.2)	0	1 (0.1)
OTHER ANTIDIARRHEALS	2 (0.4)	0	2 (0.3)
ACACIA SPP.;GALACTOSE;GLUCOSE;HERBAL NOS;LACTOSE;TRANS-GALACTOOLIGOSACCHARIDE	1 (0.2)	0	1 (0.1)
RACECADOTRIL	1 (0.2)	0	1 (0.1)
OTHER ANTIEMETICS	83 (15.7)	17 (8.3)	100 (13.6)
PROCHLORPERAZINE	47 (8.9)	8 (3.9)	55 (7.5)
PROCHLORPERAZINE EDISYLATE	16 (3.0)	5 (2.4)	21 (2.9)
PROMETHAZINE	8 (1.5)	3 (1.5)	11 (1.5)
HYOSCINE	4 (0.8)	0	4 (0.5)
METOPIMAZINE	3 (0.6)	0	3 (0.4)
DIMENHYDRINATE	2 (0.4)	2 (1.0)	4 (0.5)
PROCHLORPERAZINE MALEATE	2 (0.4)	0	2 (0.3)
PROMETHAZINE HYDROCHLORIDE	2 (0.4)	0	2 (0.3)
MECLOZINE	1 (0.2)	1 (0.5)	2 (0.3)
TRIMETHOBENZAMIDE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	0	1 (0.5)	1 (0.1)
MORNIFLUMATE	0	1 (0.5)	1 (0.1)

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Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-10 2021-09-22 16:45

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
OTHER BLOOD PRODUCTS	80 (15.1)	11 (5.4)	91 (12.4)
BLOOD CELLS, PACKED HUMAN	36 (6.8)	4 (2.0)	40 (5.4)
RED BLOOD CELLS	35 (6.6)	7 (3.4)	42 (5.7)
BLOOD, WHOLE	9 (1.7)	2 (1.0)	11 (1.5)
PLATELETS	9 (1.7)	0	9 (1.2)
RED BLOOD CELLS, CONCENTRATED	5 (0.9)	0	5 (0.7)
PLATELETS, CONCENTRATED	2 (0.4)	0	2 (0.3)
PLASMA	1 (0.2)	0	1 (0.1)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	184 (34.8)	80 (39.0)	264 (36.0)
DENOSUMAB	184 (34.8)	80 (39.0)	264 (36.0)
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	1 (0.2)	0	1 (0.1)
LYCOPENE	1 (0.2)	0	1 (0.1)
OTHER HORMONE ANTAGONISTS AND RELATED AGENTS	146 (27.6)	76 (37.1)	222 (30.2)
ABIRATERONE ACETATE	87 (16.4)	49 (23.9)	136 (18.5)
ABIRATERONE	47 (8.9)	23 (11.2)	70 (9.5)
DEGARELIX ACETATE	12 (2.3)	1 (0.5)	13 (1.8)
DEGARELIX	6 (1.1)	5 (2.4)	11 (1.5)
OTHER OPIOIDS	59 (11.2)	20 (9.8)	79 (10.8)
TRAMADOL	55 (10.4)	16 (7.8)	71 (9.7)
TRAMADOL HYDROCHLORIDE	5 (0.9)	4 (2.0)	9 (1.2)
TAPENTADOL	1 (0.2)	0	1 (0.1)
OXICAMS	5 (0.9)	6 (2.9)	11 (1.5)
MELOXICAM	5 (0.9)	6 (2.9)	11 (1.5)
PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN	0	2 (1.0)	2 (0.3)

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PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN			
(Continued)			
LEVOMEPPROMAZINE	0	2 (1.0)	2 (0.3)
PHENYLPIPERIDINE DERIVATIVES	39 (7.4)	14 (6.8)	53 (7.2)
FENTANYL	38 (7.2)	14 (6.8)	52 (7.1)
FENTANYL CITRATE	3 (0.6)	0	3 (0.4)
PREGNADIEN DERIVATIVES	0	1 (0.5)	1 (0.1)
MEGESTROL ACETATE	0	1 (0.5)	1 (0.1)
PROGESTOGENS	4 (0.8)	2 (1.0)	6 (0.8)
MEDROXYPROGESTERONE ACETATE	2 (0.4)	0	2 (0.3)
MEDROXYPROGESTERONE	1 (0.2)	0	1 (0.1)
MEGESTROL	1 (0.2)	2 (1.0)	3 (0.4)
PROPIONIC ACID DERIVATIVES	144 (27.2)	56 (27.3)	200 (27.2)
IBUPROFEN	97 (18.3)	42 (20.5)	139 (18.9)
NAPROXEN	27 (5.1)	10 (4.9)	37 (5.0)
NAPROXEN SODIUM	25 (4.7)	6 (2.9)	31 (4.2)
KETOPROFEN	3 (0.6)	1 (0.5)	4 (0.5)
IBUPROFEN;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.2)	0	1 (0.1)
PROPULSIVES	74 (14.0)	13 (6.3)	87 (11.9)
METOCLOPRAMIDE	33 (6.2)	6 (2.9)	39 (5.3)
METOCLOPRAMIDE HYDROCHLORIDE	29 (5.5)	4 (2.0)	33 (4.5)
DOMPERIDONE	11 (2.1)	1 (0.5)	12 (1.6)
ALIZAPRIDE	4 (0.8)	2 (1.0)	6 (0.8)
ALIZAPRIDE HYDROCHLORIDE	0	1 (0.5)	1 (0.1)
PYRAZOLONES	1 (0.2)	0	1 (0.1)
METAMIZOLE SODIUM	1 (0.2)	0	1 (0.1)
SALICYLIC ACID AND DERIVATIVES	9 (1.7)	2 (1.0)	11 (1.5)
ACETYLSALICYLIC ACID	5 (0.9)	2 (1.0)	7 (1.0)

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SALICYLIC ACID AND DERIVATIVES (Continued)			
ACETYLSALICYLIC ACID;CAFFEINE	2 (0.4)	0	2 (0.3)
ACETYLSALICYLIC ACID;CITRIC ACID;SODIUM BICARBONATE	2 (0.4)	0	2 (0.3)
SEROTONIN (5HT3) ANTAGONISTS	270 (51.0)	35 (17.1)	305 (41.6)
ONDANSETRON	261 (49.3)	32 (15.6)	293 (39.9)
ONDANSETRON HYDROCHLORIDE	7 (1.3)	2 (1.0)	9 (1.2)
GRANISETRON	4 (0.8)	1 (0.5)	5 (0.7)
GRANISETRON HYDROCHLORIDE	4 (0.8)	1 (0.5)	5 (0.7)
PALONOSETRON HYDROCHLORIDE	4 (0.8)	0	4 (0.5)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	15 (2.8)	1 (0.5)	16 (2.2)
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE	10 (1.9)	1 (0.5)	11 (1.5)
ELECTROLYTES NOS	2 (0.4)	0	2 (0.3)
GLUCOSE;SODIUM CHLORIDE	2 (0.4)	0	2 (0.3)
SODIUM CHLORIDE	2 (0.4)	0	2 (0.3)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM	1 (0.2)	0	1 (0.1)
CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	1 (0.2)	0	1 (0.1)
GLUCONATE SODIUM;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	1 (0.2)	0	1 (0.1)
GLUCOSE;POTASSIUM CHLORIDE	1 (0.2)	0	1 (0.1)
TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	16 (3.0)	11 (5.4)	27 (3.7)
DUTASTERIDE	9 (1.7)	4 (2.0)	13 (1.8)
FINASTERIDE	7 (1.3)	7 (3.4)	14 (1.9)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	40 (7.6)	24 (11.7)	64 (8.7)
CYANOCOBALAMIN	34 (6.4)	21 (10.2)	55 (7.5)
VITAMIN B12 NOS	6 (1.1)	1 (0.5)	7 (1.0)
HYDROXOCOBALAMIN	0	2 (1.0)	2 (0.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications indicated as BSC/BSoC are all medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHODrug Global version Mar 2021 B3.

Output ID: T-1-3-10 2021-09-22 16:45

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-10 Concomitant medications indicated as study best supportive/best standard of care (FAS safety set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
VITAMIN K	3 (0.6)	1 (0.5)	4 (0.5)
PHYTOMENADIONE	2 (0.4)	0	2 (0.3)
MENAQUINONE	1 (0.2)	0	1 (0.1)
VITAMIN K NOS	0	1 (0.5)	1 (0.1)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications indicated as BSC/BSoC are all medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of randomized treatment or starting prior to and continuing after the start of randomized treatment but not more than 30 days after end of randomized treatment.

Coded using WHODrug Global version Mar 2021 B3.

Output ID: T-1-3-10 2021-09-22 16:45

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-10s Concomitant medications indicated as study best supportive/best standard of care (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Number of patients with at least one concomitant medication indicated as study BSC/BSoC	30 (100)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES DICLOFENAC	2 (6.7) 2 (6.7)
ALPHA-ADRENOCEPTOR ANTAGONISTS TAMSULOSIN TAMSULOSIN HYDROCHLORIDE	4 (13.3) 3 (10.0) 1 (3.3)
ANTI-ANDROGENS ENZALUTAMIDE BICALUTAMIDE	11 (36.7) 10 (33.3) 1 (3.3)
BISPHOSPHONATES ZOLEDRONIC ACID ZOLEDRONIC ACID MONOHYDRATE	3 (10.0) 2 (6.7) 1 (3.3)
COLONY STIMULATING FACTORS GRANULOCYTE COLONY STIMULATING FACTOR LIPEGFILGRASTIM	2 (6.7) 1 (3.3) 1 (3.3)
COXIBS CELECOXIB ETORICOXIB	2 (6.7) 1 (3.3) 1 (3.3)
DIPHENYLPROPYLAMINE DERIVATIVES LEVOMETHADONE HYDROCHLORIDE METHADONE HYDROCHLORIDE PIRITRAMIDE	3 (10.0) 1 (3.3) 1 (3.3) 1 (3.3)
ELECTROLYTE SOLUTIONS SODIUM CHLORIDE	9 (30.0) 9 (30.0)
GLUCOCORTICOIDS	15 (50.0)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications indicated as BSC/BSoC are all medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-10s 2021-09-22 16:45

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-10s Concomitant medications indicated as study best supportive/best standard of care (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
GLUCOCORTICOIDS (Continued)	
DEXAMETHASONE	10 (33.3)
PREDNISOLONE	8 (26.7)
PREDNISONE	1 (3.3)
GONADOTROPIN RELEASING HORMONE ANALOGUES	27 (90.0)
LEUPRORELIN ACETATE	10 (33.3)
LEUPRORELIN	9 (30.0)
TRIPTORELIN EMBONATE	3 (10.0)
BUSERELIN	2 (6.7)
GONADOTROPIN RELEASING HORMONE ANALOGUES	2 (6.7)
BUSERELIN ACETATE	1 (3.3)
GONADOTROPIN-RELEASING HORMONES	1 (3.3)
GONADORELIN DIACETATE TETRAHYDRATE	1 (3.3)
NATURAL OPIUM ALKALOIDS	8 (26.7)
HYDROMORPHONE	5 (16.7)
HYDROMORPHONE HYDROCHLORIDE	3 (10.0)
OXYCODONE HYDROCHLORIDE	3 (10.0)
MORPHINE SULFATE	1 (3.3)
NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE	1 (3.3)
OTHER ANALGESICS AND ANTIPYRETICS	7 (23.3)
PREGABALIN	6 (20.0)
AMITRIPTYLINE	1 (3.3)
AMITRIPTYLINE HYDROCHLORIDE	1 (3.3)
OTHER ANTIDIARRHEALS	1 (3.3)
COLESTYRAMINE	1 (3.3)
OTHER BLOOD PRODUCTS	5 (16.7)
RED BLOOD CELLS, CONCENTRATED	4 (13.3)
PLATELETS	2 (6.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications indicated as BSC/BSoC are all medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-10s 2021-09-22 16:45

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-10s Concomitant medications indicated as study best supportive/best standard of care (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
OTHER BLOOD PRODUCTS (Continued)	
RED BLOOD CELLS	2 (6.7)
PLATELETS, CONCENTRATED	1 (3.3)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	15 (50.0)
DENOSUMAB	15 (50.0)
OTHER HORMONE ANTAGONISTS AND RELATED AGENTS	
ABIRATERONE	2 (6.7)
ABIRATERONE ACETATE	1 (3.3)
ABIRATERONE ACETATE	1 (3.3)
OTHER OPIOIDS	4 (13.3)
NALOXONE HYDROCHLORIDE; TILIDINE HYDROCHLORIDE	1 (3.3)
TAPENTADOL HYDROCHLORIDE	1 (3.3)
TRAMADOL	1 (3.3)
TRAMADOL HYDROCHLORIDE	1 (3.3)
PHENYLPIPERIDINE DERIVATIVES	3 (10.0)
FENTANYL	2 (6.7)
PETHIDINE HYDROCHLORIDE	1 (3.3)
PROPIONIC ACID DERIVATIVES	10 (33.3)
IBUPROFEN	10 (33.3)
PROPULSIVES	7 (23.3)
METOCLOPRAMIDE	7 (23.3)
PYRAZOLONES	18 (60.0)
METAMIZOLE SODIUM	16 (53.3)
METAMIZOLE	4 (13.3)
SEROTONIN (5HT3) ANTAGONISTS	20 (66.7)
ONDANSETRON	17 (56.7)
GRANISETRON	5 (16.7)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications indicated as BSC/BSoC are all medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

Output ID: T-1-3-10s 2021-09-22 16:45

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-10s Concomitant medications indicated as study best supportive/best standard of care (Sub-study safety analysis set)

ATC level 4 Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	14 (46.7)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	10 (33.3)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;MALIC ACID;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	5 (16.7)
ELECTROLYTES NOS	1 (3.3)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	2 (6.7)
CYANOCOBALAMIN	1 (3.3)
CYANOCOBALAMIN;FOLIC ACID;URIDINE TRIPHOSPHATE SODIUM	1 (3.3)

ATC levels are presented alphabetically; preferred terms within ATC level are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

A medication/therapy can appear in more than one ATC level.

Every patient is counted a single time for each applicable specific medication category.

Concomitant medications indicated as BSC/BSoC are all medications indicated as BSC/BSoC (per sponsor pre-specified list) starting on or after the start of study treatment or starting prior to and continuing after the start of study treatment but not more than 30 days after end of study treatment.

Coded using WHO Drug Global version Mar 2021 B3.

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Source data: adsl.xpt, adcm.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 1-3-11 Concurrent radiotherapy indicated as study best supportive/best standard of care (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Number of patients with at least one concurrent radiotherapy indicated as BSC/BSoC	82 (15.5)	35 (17.1)	117 (15.9)
Site of radiotherapy			
Back	29 (5.5)	12 (5.9)	41 (5.6)
Other	10 (1.9)	4 (2.0)	14 (1.9)
Femur	9 (1.7)	0	9 (1.2)
Pelvic bone	9 (1.7)	5 (2.4)	14 (1.9)
Vertebral column	7 (1.3)	6 (2.9)	13 (1.8)
Bone	6 (1.1)	1 (0.5)	7 (1.0)
Hip	5 (0.9)	2 (1.0)	7 (1.0)
Iliac crest	5 (0.9)	0	5 (0.7)
Rib	5 (0.9)	1 (0.5)	6 (0.8)
Prostate gland	4 (0.8)	3 (1.5)	7 (1.0)
Sacrum	4 (0.8)	2 (1.0)	6 (0.8)
Lower extremity bone	3 (0.6)	0	3 (0.4)
Scapula	3 (0.6)	2 (1.0)	5 (0.7)
Skull	2 (0.4)	2 (1.0)	4 (0.5)
Lung	1 (0.2)	0	1 (0.1)
Supraclavicular lymph node	1 (0.2)	0	1 (0.1)
Lymph node	0	1 (0.5)	1 (0.1)
Neck	0	1 (0.5)	1 (0.1)

Site of radiotherapy are sorted in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.
Every patient is counted a single time for each site of radiotherapy.

Concurrent radiotherapy indicated as BSC/BSoC are all radiotherapies indicated as BSC/BSoC (reported by investigator) starting on or after the start of randomized treatment or starting prior to and continuing after start of randomized treatment but not more than 30 days after end of randomized treatment.

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-11s Concurrent radiotherapy indicated as study best supportive/best standard of care (Sub-study safety analysis set)

No data to report

Site of radiotherapy are sorted in descending frequency, as reported in 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each site of radiotherapy.

Concurrent radiotherapy indicated as BSC/BSoC are all radiotherapies indicated as BSC/BSoC (reported by investigator) starting on or after the start of study treatment or starting prior to and continuing after start of study treatment but not more than 30 days after end of study treatment.

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-12 Concurrent procedures other than radiotherapy indicated as study best supportive/best standard of care (FAS safety set)

System organ class Preferred term	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Number of patients with at least one concurrent procedure other than radiotherapy indicated as study BSC/BSoC	24 (4.5)	5 (2.4)	29 (4.0)
Investigations	5 (0.9)	0	5 (0.7)
Aspiration pleural cavity	2 (0.4)	0	2 (0.3)
Biopsy	1 (0.2)	0	1 (0.1)
Computerised tomogram thorax	1 (0.2)	0	1 (0.1)
Paracentesis	1 (0.2)	0	1 (0.1)
Surgical and medical procedures	19 (3.6)	5 (2.4)	24 (3.3)
Vertebroplasty	4 (0.8)	1 (0.5)	5 (0.7)
Cryotherapy	3 (0.6)	0	3 (0.4)
Spinal decompression	2 (0.4)	0	2 (0.3)
Spinal fusion surgery	2 (0.4)	2 (1.0)	4 (0.5)
Spinal laminectomy	2 (0.4)	1 (0.5)	3 (0.4)
Transurethral prostatectomy	2 (0.4)	0	2 (0.3)
Appendectomy	1 (0.2)	0	1 (0.1)
Epidural injection	1 (0.2)	0	1 (0.1)
High frequency ablation	1 (0.2)	0	1 (0.1)
Internal fixation of fracture	1 (0.2)	0	1 (0.1)
Intramedullary rod insertion	1 (0.2)	0	1 (0.1)
Limb immobilisation	1 (0.2)	0	1 (0.1)
Liver ablation	1 (0.2)	0	1 (0.1)
Open reduction of fracture	1 (0.2)	0	1 (0.1)
Transurethral bladder resection	1 (0.2)	0	1 (0.1)
Tumour excision	1 (0.2)	0	1 (0.1)
Ureteral stent insertion	1 (0.2)	1 (0.5)	2 (0.3)
Ureteral stent removal	1 (0.2)	0	1 (0.1)

System organ classes are presented alphabetically; preferred terms within system organ class are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable system organ class and preferred term.

Concurrent procedures indicated as BSC/BSoC are all procedures indicated as BSC/BSoC (reported by investigator) starting on or after the start of randomized treatment or starting prior to and continuing after randomized treatment but not more than 30 days after end of randomized treatment.

Coded using MedDRA version 24.0.

Output ID: T-1-3-12 2021-09-22 16:46

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 1-3-12s Concurrent procedures other than radiotherapy indicated as study best supportive/best standard of care (Sub-study safety analysis set)

No data to report

System organ classes are presented alphabetically; preferred terms within system organ class are sorted by descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable system organ class and preferred term.

Concurrent procedures indicated as BSC/BSoC are all procedures indicated as BSC/BSoC (reported by investigator) starting on or after the start of study treatment or starting prior to and continuing after study treatment but not more than 30 days after end of study treatment.

Coded using MedDRA version 24.0.

Output ID: T-1-3-12s 2021-09-22 16:46

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Source data: adsl.xpt, adpr.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-1-1 Overview of randomized treatment-emergent adverse events (FAS safety set)

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
TEAE	519 (98.1)	170 (82.9)	689 (93.9)	519 (98.1)	170 (82.9)	689 (93.9)
Serious TEAE*	192 (36.3)	57 (27.8)	249 (33.9)	195 (36.9)	58 (28.3)	253 (34.5)
Grade 3/4/5 TEAE*	279 (52.7)	78 (38.0)	357 (48.6)	281 (53.1)	79 (38.5)	360 (49.0)
Drug-related TEAE	451 (85.3)	59 (28.8)	510 (69.5)	451 (85.3)	59 (28.8)	510 (69.5)
Serious drug-related TEAE*	49 (9.3)	5 (2.4)	54 (7.4)	51 (9.6)	5 (2.4)	56 (7.6)
Drug-related grade 3/4/5 TEAE*	150 (28.4)	8 (3.9)	158 (21.5)	151 (28.5)	8 (3.9)	159 (21.7)
TEAE leading to reduction of 177Lu-PSMA-617	30 (5.7)	0	30 (4.1)	30 (5.7)	0	30 (4.1)
TEAE leading to reduction of BSC/BSoC	17 (3.2)	7 (3.4)	24 (3.3)	17 (3.2)	7 (3.4)	24 (3.3)
TEAE leading to interruption of 177Lu-PSMA-617	85 (16.1)	2 (1.0)	87 (11.9)	85 (16.1)	2 (1.0)	87 (11.9)
TEAE leading to interruption of BSC/BSoC	50 (9.5)	14 (6.8)	64 (8.7)	50 (9.5)	14 (6.8)	64 (8.7)
TEAE leading to discontinuation of 177Lu-PSMA-617	63 (11.9)	1 (0.5)	64 (8.7)	63 (11.9)	1 (0.5)	64 (8.7)
TEAE leading to discontinuation of BSC/BSoC*	45 (8.5)	16 (7.8)	61 (8.3)	47 (8.9)	16 (7.8)	63 (8.6)
Fatal TEAE	19 (3.6)	6 (2.9)	25 (3.4)	19 (3.6)	6 (2.9)	25 (3.4)

Randomized treatment-emergent adverse event (TEAE) = any AE that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment.

A patient with multiple grades for an AE is only counted under the maximum grade.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-1-2021-09-22 16:44

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-1-1s Overview of study treatment-emergent adverse events (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
TEAE	30 (100)
Serious TEAE	8 (26.7)
Grade 3/4/5 TEAE	11 (36.7)
Drug-related TEAE	19 (63.3)
Serious drug-related TEAE	2 (6.7)
Drug-related grade 3/4/5 TEAE	6 (20.0)
TEAE leading to reduction of 177Lu-PSMA-617	2 (6.7)
TEAE leading to reduction of BSC/BSoC	1 (3.3)
TEAE leading to interruption of 177Lu-PSMA-617	4 (13.3)
TEAE leading to interruption of BSC/BSoC	1 (3.3)
TEAE leading to discontinuation of 177Lu-PSMA-617	2 (6.7)
TEAE leading to discontinuation of BSC/BSoC	0
Fatal TEAE	2 (6.7)

Study treatment-emergent adverse event (TEAE) = any AE that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment.

A patient with multiple grades for an AE is only counted under the maximum grade.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-2 Randomized treatment-emergent adverse events by system organ class (FAS safety set)

System organ class	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event*	519 (98.1)	279 (52.7)	170 (82.9)	78 (38.0)	689 (93.9)	357 (48.6)	519 (98.1)	281 (53.1)	170 (82.9)	79 (38.5)	689 (93.9)	360 (49.0)
Gastrointestinal disorders*	399 (75.4)	31 (5.9)	65 (31.7)	6 (2.9)	464 (63.2)	37 (5.0)	399 (75.4)	33 (6.2)	65 (31.7)	6 (2.9)	464 (63.2)	39 (5.3)
General disorders and administration site conditions*	324 (61.2)	50 (9.5)	79 (38.5)	10 (4.9)	403 (54.9)	60 (8.2)	325 (61.4)	50 (9.5)	80 (39.0)	10 (4.9)	405 (55.2)	60 (8.2)
Musculoskeletal and connective tissue disorders*	311 (58.8)	48 (9.1)	83 (40.5)	15 (7.3)	394 (53.7)	63 (8.6)	315 (59.5)	49 (9.3)	83 (40.5)	16 (7.8)	398 (54.2)	65 (8.9)
Blood and lymphatic system disorders	253 (47.8)	127 (24.0)	37 (18.0)	14 (6.8)	290 (39.5)	141 (19.2)	253 (47.8)	127 (24.0)	37 (18.0)	14 (6.8)	290 (39.5)	141 (19.2)
Metabolism and nutrition disorders	222 (42.0)	33 (6.2)	61 (29.8)	9 (4.4)	283 (38.6)	42 (5.7)	222 (42.0)	33 (6.2)	61 (29.8)	9 (4.4)	283 (38.6)	42 (5.7)
Nervous system disorders*	183 (34.6)	37 (7.0)	55 (26.8)	17 (8.3)	238 (32.4)	54 (7.4)	183 (34.6)	37 (7.0)	55 (26.8)	18 (8.8)	238 (32.4)	55 (7.5)
Infections and infestations*	167 (31.6)	56 (10.6)	33 (16.1)	9 (4.4)	200 (27.2)	65 (8.9)	169 (31.9)	57 (10.8)	33 (16.1)	9 (4.4)	202 (27.5)	66 (9.0)
Respiratory, thoracic and mediastinal disorders*	142 (26.8)	22 (4.2)	39 (19.0)	8 (3.9)	181 (24.7)	30 (4.1)	143 (27.0)	23 (4.3)	39 (19.0)	8 (3.9)	182 (24.8)	31 (4.2)
Investigations*	125 (23.6)	15 (2.8)	31 (15.1)	3 (1.5)	156 (21.3)	18 (2.5)	127 (24.0)	15 (2.8)	33 (16.1)	4 (2.0)	160 (21.8)	19 (2.6)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

System organ class	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Renal and urinary disorders	106 (20.0)	36 (6.8)	32 (15.6)	8 (3.9)	138 (18.8)	44 (6.0)	106 (20.0)	36 (6.8)	32 (15.6)	8 (3.9)	138 (18.8)	44 (6.0)
Injury, poisoning and procedural complications*	98 (18.5)	17 (3.2)	24 (11.7)	6 (2.9)	122 (16.6)	23 (3.1)	99 (18.7)	17 (3.2)	24 (11.7)	6 (2.9)	123 (16.8)	23 (3.1)
Vascular disorders*	84 (15.9)	29 (5.5)	28 (13.7)	6 (2.9)	112 (15.3)	35 (4.8)	87 (16.4)	29 (5.5)	28 (13.7)	6 (2.9)	115 (15.7)	35 (4.8)
Psychiatric disorders*	68 (12.9)	8 (1.5)	22 (10.7)	2 (1.0)	90 (12.3)	10 (1.4)	69 (13.0)	8 (1.5)	22 (10.7)	2 (1.0)	91 (12.4)	10 (1.4)
Skin and subcutaneous tissue disorders	69 (13.0)	0	12 (5.9)	0	81 (11.0)	0	69 (13.0)	0	12 (5.9)	0	81 (11.0)	0
Eye disorders	53 (10.0)	6 (1.1)	9 (4.4)	0	62 (8.4)	6 (0.8)	53 (10.0)	6 (1.1)	9 (4.4)	0	62 (8.4)	6 (0.8)
Cardiac disorders	25 (4.7)	11 (2.1)	6 (2.9)	3 (1.5)	31 (4.2)	14 (1.9)	25 (4.7)	11 (2.1)	6 (2.9)	3 (1.5)	31 (4.2)	14 (1.9)
Reproductive system and breast disorders	17 (3.2)	2 (0.4)	0	0	17 (2.3)	2 (0.3)	17 (3.2)	2 (0.4)	0	0	17 (2.3)	2 (0.3)
Ear and labyrinth disorders	16 (3.0)	0	3 (1.5)	0	19 (2.6)	0	16 (3.0)	0	3 (1.5)	0	19 (2.6)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)*	15 (2.8)	4 (0.8)	2 (1.0)	1 (0.5)	17 (2.3)	5 (0.7)	16 (3.0)	5 (0.9)	2 (1.0)	1 (0.5)	18 (2.5)	6 (0.8)
Hepatobiliary disorders	13 (2.5)	5 (0.9)	8 (3.9)	3 (1.5)	21 (2.9)	8 (1.1)	13 (2.5)	5 (0.9)	8 (3.9)	3 (1.5)	21 (2.9)	8 (1.1)
Endocrine disorders	8 (1.5)	1 (0.2)	2 (1.0)	1 (0.5)	10 (1.4)	2 (0.3)	8 (1.5)	1 (0.2)	2 (1.0)	1 (0.5)	10 (1.4)	2 (0.3)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

System organ class	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Surgical and medical procedures	4 (0.8)	2 (0.4)	0	0	4 (0.5)	2 (0.3)	4 (0.8)	2 (0.4)	0	0	4 (0.5)	2 (0.3)
Congenital, familial and genetic disorders	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Product issues	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Immune system disorders	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

A patient with multiple grades for a SOC is only counted under the maximum grade.

System organ classes are sorted in descending frequency of 'All Grades' column, as reported in the Safety Update 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-1-2 2021-09-22 16:40

...\\BIOMETRY\\PROJECTSPSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aesoc.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-1-2s Study treatment-emergent adverse events by system organ class (Sub-study safety analysis set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	30 (100)	11 (36.7)
Gastrointestinal disorders	18 (60.0)	0
Musculoskeletal and connective tissue disorders	13 (43.3)	4 (13.3)
General disorders and administration site conditions	12 (40.0)	2 (6.7)
Blood and lymphatic system disorders	11 (36.7)	6 (20.0)
Nervous system disorders	8 (26.7)	1 (3.3)
Respiratory, thoracic and mediastinal disorders	8 (26.7)	3 (10.0)
Investigations	7 (23.3)	0
Metabolism and nutrition disorders	7 (23.3)	1 (3.3)
Psychiatric disorders	6 (20.0)	0
Infections and infestations	5 (16.7)	1 (3.3)
Renal and urinary disorders	5 (16.7)	2 (6.7)
Injury, poisoning and procedural complications	4 (13.3)	0
Skin and subcutaneous tissue disorders	4 (13.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (6.7)	1 (3.3)
Vascular disorders	2 (6.7)	0
Ear and labyrinth disorders	1 (3.3)	0
Endocrine disorders	1 (3.3)	0

A patient with multiple grades for a SOC is only counted under the maximum grade.

System organ classes are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-1-2s 2021-09-22 16:40

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aesoc.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-1-3 Randomized treatment-emergent adverse events by preferred term (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event*	519 (98.1)	279 (52.7)	170 (82.9)	78 (38.0)	689 (93.9)	357 (48.6)	519 (98.1)	281 (53.1)	170 (82.9)	79 (38.5)	689 (93.9)	360 (49.0)
Fatigue	228 (43.1)	31 (5.9)	47 (22.9)	3 (1.5)	275 (37.5)	34 (4.6)	228 (43.1)	31 (5.9)	47 (22.9)	3 (1.5)	275 (37.5)	34 (4.6)
Dry mouth	205 (38.8)	0	1 (0.5)	0	206 (28.1)	0	205 (38.8)	0	1 (0.5)	0	206 (28.1)	0
Nausea*	187 (35.3)	7 (1.3)	34 (16.6)	1 (0.5)	221 (30.1)	8 (1.1)	188 (35.5)	7 (1.3)	34 (16.6)	1 (0.5)	222 (30.2)	8 (1.1)
Anaemia	168 (31.8)	68 (12.9)	27 (13.2)	10 (4.9)	195 (26.6)	78 (10.6)	168 (31.8)	68 (12.9)	27 (13.2)	10 (4.9)	195 (26.6)	78 (10.6)
Back pain*	124 (23.4)	17 (3.2)	30 (14.6)	7 (3.4)	154 (21.0)	24 (3.3)	128 (24.2)	19 (3.6)	31 (15.1)	8 (3.9)	159 (21.7)	27 (3.7)
Arthralgia*	118 (22.3)	6 (1.1)	26 (12.7)	1 (0.5)	144 (19.6)	7 (1.0)	120 (22.7)	6 (1.1)	26 (12.7)	1 (0.5)	146 (19.9)	7 (1.0)
Decreased appetite*	112 (21.2)	10 (1.9)	30 (14.6)	1 (0.5)	142 (19.3)	11 (1.5)	113 (21.4)	10 (1.9)	30 (14.6)	1 (0.5)	143 (19.5)	11 (1.5)
Constipation	107 (20.2)	6 (1.1)	23 (11.2)	1 (0.5)	130 (17.7)	7 (1.0)	107 (20.2)	6 (1.1)	23 (11.2)	1 (0.5)	130 (17.7)	7 (1.0)
Diarrhoea*	100 (18.9)	4 (0.8)	6 (2.9)	1 (0.5)	106 (14.4)	5 (0.7)	101 (19.1)	4 (0.8)	6 (2.9)	1 (0.5)	107 (14.6)	5 (0.7)
Vomiting	100 (18.9)	5 (0.9)	13 (6.3)	1 (0.5)	113 (15.4)	6 (0.8)	100 (18.9)	5 (0.9)	13 (6.3)	1 (0.5)	113 (15.4)	6 (0.8)
Thrombocytopoenia	91 (17.2)	42 (7.9)	9 (4.4)	2 (1.0)	100 (13.6)	44 (6.0)	91 (17.2)	42 (7.9)	9 (4.4)	2 (1.0)	100 (13.6)	44 (6.0)
Lymphopenia	75 (14.2)	41 (7.8)	8 (3.9)	1 (0.5)	83 (11.3)	42 (5.7)	75 (14.2)	41 (7.8)	8 (3.9)	1 (0.5)	83 (11.3)	42 (5.7)
Leukopenia	66 (12.5)	13 (2.5)	4 (2.0)	1 (0.5)	70 (9.5)	14 (1.9)	66 (12.5)	13 (2.5)	4 (2.0)	1 (0.5)	70 (9.5)	14 (1.9)
Bone pain	59 (11.2)	13 (2.5)	17 (8.3)	5 (2.4)	76 (10.4)	18 (2.5)	59 (11.2)	13 (2.5)	17 (8.3)	5 (2.4)	76 (10.4)	18 (2.5)
Urinary tract infection*	58 (11.0)	20 (3.8)	2 (1.0)	1 (0.5)	60 (8.2)	21 (2.9)	59 (11.2)	20 (3.8)	2 (1.0)	1 (0.5)	61 (8.3)	21 (2.9)
Weight decreased*	57 (10.8)	2 (0.4)	18 (8.8)	0	75 (10.2)	2 (0.3)	58 (11.0)	2 (0.4)	20 (9.8)	1 (0.5)	78 (10.6)	3 (0.4)
Dyspnoea*	53 (10.0)	7 (1.3)	20 (9.8)	3 (1.5)	73 (9.9)	10 (1.4)	53 (10.0)	8 (1.5)	20 (9.8)	3 (1.5)	73 (9.9)	11 (1.5)
Oedema peripheral	51 (9.6)	2 (0.4)	13 (6.3)	0	64 (8.7)	2 (0.3)	51 (9.6)	2 (0.4)	13 (6.3)	0	64 (8.7)	2 (0.3)
Haematuria	45 (8.5)	13 (2.5)	9 (4.4)	1 (0.5)	54 (7.4)	14 (1.9)	45 (8.5)	13 (2.5)	9 (4.4)	1 (0.5)	54 (7.4)	14 (1.9)
Neutropenia	45 (8.5)	18 (3.4)	3 (1.5)	1 (0.5)	48 (6.5)	19 (2.6)	45 (8.5)	18 (3.4)	3 (1.5)	1 (0.5)	48 (6.5)	19 (2.6)
Pain in extremity	45 (8.5)	3 (0.6)	12 (5.9)	0	57 (7.8)	3 (0.4)	45 (8.5)	3 (0.6)	12 (5.9)	0	57 (7.8)	3 (0.4)
Dizziness	44 (8.3)	5 (0.9)	9 (4.4)	0	53 (7.2)	5 (0.7)	44 (8.3)	5 (0.9)	9 (4.4)	0	53 (7.2)	5 (0.7)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Cough	42 (7.9)	0	13 (6.3)	0	55 (7.5)	0	42 (7.9)	0	13 (6.3)	0	55 (7.5)	0
Hypokalaemia	40 (7.6)	5 (0.9)	8 (3.9)	0	48 (6.5)	5 (0.7)	40 (7.6)	5 (0.9)	8 (3.9)	0	48 (6.5)	5 (0.7)
Fall*	38 (7.2)	1 (0.2)	12 (5.9)	2 (1.0)	50 (6.8)	3 (0.4)	39 (7.4)	1 (0.2)	12 (5.9)	2 (1.0)	51 (6.9)	3 (0.4)
Headache	37 (7.0)	4 (0.8)	4 (2.0)	0	41 (5.6)	4 (0.5)	37 (7.0)	4 (0.8)	4 (2.0)	0	41 (5.6)	4 (0.5)
Pyrexia*	36 (6.8)	2 (0.4)	7 (3.4)	0	43 (5.9)	2 (0.3)	37 (7.0)	2 (0.4)	7 (3.4)	0	44 (6.0)	2 (0.3)
Hypocalcaemia	36 (6.8)	4 (0.8)	7 (3.4)	1 (0.5)	43 (5.9)	5 (0.7)	36 (6.8)	4 (0.8)	7 (3.4)	1 (0.5)	43 (5.9)	5 (0.7)
Asthenia	34 (6.4)	6 (1.1)	16 (7.8)	2 (1.0)	50 (6.8)	8 (1.1)	34 (6.4)	6 (1.1)	16 (7.8)	2 (1.0)	50 (6.8)	8 (1.1)
Abdominal pain*	32 (6.0)	5 (0.9)	7 (3.4)	1 (0.5)	39 (5.3)	6 (0.8)	33 (6.2)	5 (0.9)	7 (3.4)	1 (0.5)	40 (5.4)	6 (0.8)
Pain*	33 (6.2)	7 (1.3)	9 (4.4)	1 (0.5)	42 (5.7)	8 (1.1)	33 (6.2)	7 (1.3)	10 (4.9)	1 (0.5)	43 (5.9)	8 (1.1)
Hypertension*	30 (5.7)	17 (3.2)	12 (5.9)	3 (1.5)	42 (5.7)	20 (2.7)	31 (5.9)	17 (3.2)	12 (5.9)	3 (1.5)	43 (5.9)	20 (2.7)
Blood creatinine increased	28 (5.3)	1 (0.2)	5 (2.4)	1 (0.5)	33 (4.5)	2 (0.3)	28 (5.3)	1 (0.2)	5 (2.4)	1 (0.5)	33 (4.5)	2 (0.3)
Hypophosphataemia	28 (5.3)	5 (0.9)	7 (3.4)	1 (0.5)	35 (4.8)	6 (0.8)	28 (5.3)	5 (0.9)	7 (3.4)	1 (0.5)	35 (4.8)	6 (0.8)
Insomnia	28 (5.3)	0	9 (4.4)	0	37 (5.0)	0	28 (5.3)	0	9 (4.4)	0	37 (5.0)	0
Muscular weakness*	26 (4.9)	6 (1.1)	5 (2.4)	1 (0.5)	31 (4.2)	7 (1.0)	26 (4.9)	6 (1.1)	6 (2.9)	1 (0.5)	32 (4.4)	7 (1.0)
Dysgeusia	24 (4.5)	0	3 (1.5)	0	27 (3.7)	0	24 (4.5)	0	3 (1.5)	0	27 (3.7)	0
Aspartate aminotransferase increased	22 (4.2)	4 (0.8)	5 (2.4)	1 (0.5)	27 (3.7)	5 (0.7)	22 (4.2)	4 (0.8)	5 (2.4)	1 (0.5)	27 (3.7)	5 (0.7)
Hot flush	22 (4.2)	0	8 (3.9)	0	30 (4.1)	0	22 (4.2)	0	8 (3.9)	0	30 (4.1)	0
Dehydration	21 (4.0)	8 (1.5)	6 (2.9)	3 (1.5)	27 (3.7)	11 (1.5)	21 (4.0)	8 (1.5)	6 (2.9)	3 (1.5)	27 (3.7)	11 (1.5)
Blood alkaline phosphatase increased	20 (3.8)	6 (1.1)	2 (1.0)	0	22 (3.0)	6 (0.8)	20 (3.8)	6 (1.1)	2 (1.0)	0	22 (3.0)	6 (0.8)
Hypoalbuminaemia	20 (3.8)	0	3 (1.5)	0	23 (3.1)	0	20 (3.8)	0	3 (1.5)	0	23 (3.1)	0
Hyponatraemia	20 (3.8)	1 (0.2)	9 (4.4)	3 (1.5)	29 (4.0)	4 (0.5)	20 (3.8)	1 (0.2)	9 (4.4)	3 (1.5)	29 (4.0)	4 (0.5)
Acute kidney injury	19 (3.6)	16 (3.0)	8 (3.9)	5 (2.4)	27 (3.7)	21 (2.9)	19 (3.6)	16 (3.0)	8 (3.9)	5 (2.4)	27 (3.7)	21 (2.9)
Influenza like illness	19 (3.6)	0	1 (0.5)	0	20 (2.7)	0	19 (3.6)	0	1 (0.5)	0	20 (2.7)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Muscle spasms	19 (3.6)	0	4 (2.0)	0	23 (3.1)	0	19 (3.6)	0	4 (2.0)	0	23 (3.1)	0
Myalgia	18 (3.4)	0	2 (1.0)	0	20 (2.7)	0	18 (3.4)	0	2 (1.0)	0	20 (2.7)	0
Peripheral sensory neuropathy	18 (3.4)	2 (0.4)	5 (2.4)	0	23 (3.1)	2 (0.3)	18 (3.4)	2 (0.4)	5 (2.4)	0	23 (3.1)	2 (0.3)
Abdominal pain upper	17 (3.2)	1 (0.2)	4 (2.0)	0	21 (2.9)	1 (0.1)	17 (3.2)	1 (0.2)	4 (2.0)	0	21 (2.9)	1 (0.1)
Contusion	17 (3.2)	0	3 (1.5)	0	20 (2.7)	0	17 (3.2)	0	3 (1.5)	0	20 (2.7)	0
Dyspepsia	17 (3.2)	0	1 (0.5)	0	18 (2.5)	0	17 (3.2)	0	1 (0.5)	0	18 (2.5)	0
Hyperglycaemia	17 (3.2)	1 (0.2)	1 (0.5)	0	18 (2.5)	1 (0.1)	17 (3.2)	1 (0.2)	1 (0.5)	0	18 (2.5)	1 (0.1)
Hypotension	17 (3.2)	6 (1.1)	5 (2.4)	0	22 (3.0)	6 (0.8)	17 (3.2)	6 (1.1)	5 (2.4)	0	22 (3.0)	6 (0.8)
Musculoskeletal chest pain	17 (3.2)	0	7 (3.4)	1 (0.5)	24 (3.3)	1 (0.1)	17 (3.2)	0	7 (3.4)	1 (0.5)	24 (3.3)	1 (0.1)
Nasopharyngitis	17 (3.2)	0	3 (1.5)	0	20 (2.7)	0	17 (3.2)	0	3 (1.5)	0	20 (2.7)	0
Dry eye	16 (3.0)	0	2 (1.0)	0	18 (2.5)	0	16 (3.0)	0	2 (1.0)	0	18 (2.5)	0
Flank pain	16 (3.0)	1 (0.2)	3 (1.5)	0	19 (2.6)	1 (0.1)	16 (3.0)	1 (0.2)	3 (1.5)	0	19 (2.6)	1 (0.1)
Neck pain	16 (3.0)	1 (0.2)	5 (2.4)	0	21 (2.9)	1 (0.1)	16 (3.0)	1 (0.2)	5 (2.4)	0	21 (2.9)	1 (0.1)
Alanine aminotransferase increased	15 (2.8)	2 (0.4)	6 (2.9)	2 (1.0)	21 (2.9)	4 (0.5)	15 (2.8)	2 (0.4)	6 (2.9)	2 (1.0)	21 (2.9)	4 (0.5)
Rash	15 (2.8)	0	1 (0.5)	0	16 (2.2)	0	15 (2.8)	0	1 (0.5)	0	16 (2.2)	0
Dysuria	14 (2.6)	2 (0.4)	2 (1.0)	0	16 (2.2)	2 (0.3)	14 (2.6)	2 (0.4)	2 (1.0)	0	16 (2.2)	2 (0.3)
Groin pain	14 (2.6)	2 (0.4)	1 (0.5)	0	15 (2.0)	2 (0.3)	14 (2.6)	2 (0.4)	1 (0.5)	0	15 (2.0)	2 (0.3)
Pneumonia	14 (2.6)	8 (1.5)	6 (2.9)	2 (1.0)	20 (2.7)	10 (1.4)	14 (2.6)	8 (1.5)	6 (2.9)	2 (1.0)	20 (2.7)	10 (1.4)
Hyperkalaemia	13 (2.5)	2 (0.4)	3 (1.5)	0	16 (2.2)	2 (0.3)	13 (2.5)	2 (0.4)	3 (1.5)	0	16 (2.2)	2 (0.3)
Malaise	13 (2.5)	1 (0.2)	1 (0.5)	0	14 (1.9)	1 (0.1)	13 (2.5)	1 (0.2)	1 (0.5)	0	14 (1.9)	1 (0.1)
Peripheral swelling	13 (2.5)	0	2 (1.0)	0	15 (2.0)	0	13 (2.5)	0	2 (1.0)	0	15 (2.0)	0
Taste disorder	13 (2.5)	0	0	0	13 (1.8)	0	13 (2.5)	0	0	0	13 (1.8)	0
Urinary retention	13 (2.5)	5 (0.9)	4 (2.0)	1 (0.5)	17 (2.3)	6 (0.8)	13 (2.5)	5 (0.9)	4 (2.0)	1 (0.5)	17 (2.3)	6 (0.8)
Anxiety*	11 (2.1)	1 (0.2)	5 (2.4)	0	16 (2.2)	1 (0.1)	12 (2.3)	1 (0.2)	5 (2.4)	0	17 (2.3)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Blood lactate dehydrogenase increased	12 (2.3)	0	0	0	12 (1.6)	0	12 (2.3)	0	0	0	12 (1.6)	0
Confusional state	12 (2.3)	3 (0.6)	6 (2.9)	0	18 (2.5)	3 (0.4)	12 (2.3)	3 (0.6)	6 (2.9)	0	18 (2.5)	3 (0.4)
Upper respiratory tract infection	12 (2.3)	0	1 (0.5)	0	13 (1.8)	0	12 (2.3)	0	1 (0.5)	0	13 (1.8)	0
Depression	11 (2.1)	2 (0.4)	2 (1.0)	1 (0.5)	13 (1.8)	3 (0.4)	11 (2.1)	2 (0.4)	2 (1.0)	1 (0.5)	13 (1.8)	3 (0.4)
Dyspnoea exertional	11 (2.1)	0	2 (1.0)	0	13 (1.8)	0	11 (2.1)	0	2 (1.0)	0	13 (1.8)	0
Paraesthesia	11 (2.1)	1 (0.2)	6 (2.9)	0	17 (2.3)	1 (0.1)	11 (2.1)	1 (0.2)	6 (2.9)	0	17 (2.3)	1 (0.1)
Sepsis	11 (2.1)	10 (1.9)	3 (1.5)	3 (1.5)	14 (1.9)	13 (1.8)	11 (2.1)	10 (1.9)	3 (1.5)	3 (1.5)	14 (1.9)	13 (1.8)
Vertigo	11 (2.1)	0	0	0	11 (1.5)	0	11 (2.1)	0	0	0	11 (1.5)	0
Gastrooesophageal reflux disease	10 (1.9)	1 (0.2)	1 (0.5)	0	11 (1.5)	1 (0.1)	10 (1.9)	1 (0.2)	1 (0.5)	0	11 (1.5)	1 (0.1)
Hypercalcaemia	10 (1.9)	1 (0.2)	4 (2.0)	0	14 (1.9)	1 (0.1)	10 (1.9)	1 (0.2)	4 (2.0)	0	14 (1.9)	1 (0.1)
Hypoesthesia	10 (1.9)	0	3 (1.5)	0	13 (1.8)	0	10 (1.9)	0	3 (1.5)	0	13 (1.8)	0
Pulmonary embolism	10 (1.9)	8 (1.5)	2 (1.0)	2 (1.0)	12 (1.6)	10 (1.4)	10 (1.9)	8 (1.5)	2 (1.0)	2 (1.0)	12 (1.6)	10 (1.4)
Urinary incontinence	10 (1.9)	1 (0.2)	3 (1.5)	0	13 (1.8)	1 (0.1)	10 (1.9)	1 (0.2)	3 (1.5)	0	13 (1.8)	1 (0.1)
Chest pain	9 (1.7)	0	0	0	9 (1.2)	0	9 (1.7)	0	0	0	9 (1.2)	0
Pleural effusion	9 (1.7)	3 (0.6)	2 (1.0)	1 (0.5)	11 (1.5)	4 (0.5)	9 (1.7)	3 (0.6)	2 (1.0)	1 (0.5)	11 (1.5)	4 (0.5)
Pollakiuria	9 (1.7)	0	7 (3.4)	0	16 (2.2)	0	9 (1.7)	0	7 (3.4)	0	16 (2.2)	0
Stomatitis	9 (1.7)	1 (0.2)	0	0	9 (1.2)	1 (0.1)	9 (1.7)	1 (0.2)	0	0	9 (1.2)	1 (0.1)
Vision blurred	9 (1.7)	2 (0.4)	2 (1.0)	0	11 (1.5)	2 (0.3)	9 (1.7)	2 (0.4)	2 (1.0)	0	11 (1.5)	2 (0.3)
Deep vein thrombosis*	7 (1.3)	2 (0.4)	2 (1.0)	0	9 (1.2)	2 (0.3)	8 (1.5)	2 (0.4)	2 (1.0)	0	10 (1.4)	2 (0.3)
Hypomagnesae mia	8 (1.5)	0	0	0	8 (1.1)	0	8 (1.5)	0	0	0	8 (1.1)	0
Limb injury	8 (1.5)	0	1 (0.5)	0	9 (1.2)	0	8 (1.5)	0	1 (0.5)	0	9 (1.2)	0
Pancytopenia	8 (1.5)	6 (1.1)	0	0	8 (1.1)	6 (0.8)	8 (1.5)	6 (1.1)	0	0	8 (1.1)	6 (0.8)

Page 4 of 31

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Spinal compression fracture	8 (1.5)	2 (0.4)	1 (0.5)	0	9 (1.2)	2 (0.3)	8 (1.5)	2 (0.4)	1 (0.5)	0	9 (1.2)	2 (0.3)
Abdominal discomfort	7 (1.3)	0	1 (0.5)	0	8 (1.1)	0	7 (1.3)	0	1 (0.5)	0	8 (1.1)	0
Cataract	7 (1.3)	2 (0.4)	0	0	7 (1.0)	2 (0.3)	7 (1.3)	2 (0.4)	0	0	7 (1.0)	2 (0.3)
Chills	7 (1.3)	0	2 (1.0)	0	9 (1.2)	0	7 (1.3)	0	2 (1.0)	0	9 (1.2)	0
Dry skin	7 (1.3)	0	2 (1.0)	0	9 (1.2)	0	7 (1.3)	0	2 (1.0)	0	9 (1.2)	0
Dysphagia	7 (1.3)	0	2 (1.0)	0	9 (1.2)	0	7 (1.3)	0	2 (1.0)	0	9 (1.2)	0
Epistaxis	7 (1.3)	1 (0.2)	0	0	7 (1.0)	1 (0.1)	7 (1.3)	1 (0.2)	0	0	7 (1.0)	1 (0.1)
Hydronephrosis	7 (1.3)	3 (0.6)	1 (0.5)	1 (0.5)	8 (1.1)	4 (0.5)	7 (1.3)	3 (0.6)	1 (0.5)	1 (0.5)	8 (1.1)	4 (0.5)
Hyperbilirubinemia	7 (1.3)	3 (0.6)	3 (1.5)	1 (0.5)	10 (1.4)	4 (0.5)	7 (1.3)	3 (0.6)	3 (1.5)	1 (0.5)	10 (1.4)	4 (0.5)
Musculoskeletal stiffness	7 (1.3)	0	0	0	7 (1.0)	0	7 (1.3)	0	0	0	7 (1.0)	0
Nasal congestion*	6 (1.1)	0	1 (0.5)	0	7 (1.0)	0	7 (1.3)	0	1 (0.5)	0	8 (1.1)	0
Spinal cord compression*	7 (1.3)	7 (1.3)	11 (5.4)	11 (5.4)	18 (2.5)	18 (2.5)	7 (1.3)	7 (1.3)	12 (5.9)	12 (5.9)	19 (2.6)	19 (2.6)
Syncope	7 (1.3)	6 (1.1)	0	0	7 (1.0)	6 (0.8)	7 (1.3)	6 (1.1)	0	0	7 (1.0)	6 (0.8)
Visual impairment	7 (1.3)	0	0	0	7 (1.0)	0	7 (1.3)	0	0	0	7 (1.0)	0
Abdominal distension	6 (1.1)	0	4 (2.0)	0	10 (1.4)	0	6 (1.1)	0	4 (2.0)	0	10 (1.4)	0
Ascites	6 (1.1)	1 (0.2)	0	0	6 (0.8)	1 (0.1)	6 (1.1)	1 (0.2)	0	0	6 (0.8)	1 (0.1)
Cystitis	6 (1.1)	1 (0.2)	0	0	6 (0.8)	1 (0.1)	6 (1.1)	1 (0.2)	0	0	6 (0.8)	1 (0.1)
Gout	6 (1.1)	1 (0.2)	0	0	6 (0.8)	1 (0.1)	6 (1.1)	1 (0.2)	0	0	6 (0.8)	1 (0.1)
Musculoskeletal discomfort	6 (1.1)	0	0	0	6 (0.8)	0	6 (1.1)	0	0	0	6 (0.8)	0
Oral candidiasis	6 (1.1)	0	0	0	6 (0.8)	0	6 (1.1)	0	0	0	6 (0.8)	0
Oropharyngeal pain	6 (1.1)	0	0	0	6 (0.8)	0	6 (1.1)	0	0	0	6 (0.8)	0
Osteonecrosis of jaw*	4 (0.8)	0	1 (0.5)	1 (0.5)	5 (0.7)	1 (0.1)	6 (1.1)	0	1 (0.5)	1 (0.5)	7 (1.0)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Pain in jaw	6 (1.1)	0	2 (1.0)	0	8 (1.1)	0	6 (1.1)	0	2 (1.0)	0	8 (1.1)	0
Spinal pain	6 (1.1)	0	0	0	6 (0.8)	0	6 (1.1)	0	0	0	6 (0.8)	0
Urinary tract obstruction	6 (1.1)	5 (0.9)	0	0	6 (0.8)	5 (0.7)	6 (1.1)	5 (0.9)	0	0	6 (0.8)	5 (0.7)
Abdominal pain lower*	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0	5 (0.9)	1 (0.2)	2 (1.0)	0	7 (1.0)	1 (0.1)
Chronic kidney disease	5 (0.9)	1 (0.2)	0	0	5 (0.7)	1 (0.1)	5 (0.9)	1 (0.2)	0	0	5 (0.7)	1 (0.1)
Coccydynia	5 (0.9)	0	0	0	5 (0.7)	0	5 (0.9)	0	0	0	5 (0.7)	0
Dysarthria	5 (0.9)	1 (0.2)	1 (0.5)	0	6 (0.8)	1 (0.1)	5 (0.9)	1 (0.2)	1 (0.5)	0	6 (0.8)	1 (0.1)
Gamma-glutamyltransferase increased	5 (0.9)	3 (0.6)	0	0	5 (0.7)	3 (0.4)	5 (0.9)	3 (0.6)	0	0	5 (0.7)	3 (0.4)
Hip fracture	5 (0.9)	2 (0.4)	0	0	5 (0.7)	2 (0.3)	5 (0.9)	2 (0.4)	0	0	5 (0.7)	2 (0.3)
Mental status changes	5 (0.9)	3 (0.6)	0	0	5 (0.7)	3 (0.4)	5 (0.9)	3 (0.6)	0	0	5 (0.7)	3 (0.4)
Night sweats	5 (0.9)	0	1 (0.5)	0	6 (0.8)	0	5 (0.9)	0	1 (0.5)	0	6 (0.8)	0
Pelvic pain	5 (0.9)	0	0	0	5 (0.7)	0	5 (0.9)	0	0	0	5 (0.7)	0
Productive cough	5 (0.9)	0	0	0	5 (0.7)	0	5 (0.9)	0	0	0	5 (0.7)	0
Sciatica	5 (0.9)	0	1 (0.5)	0	6 (0.8)	0	5 (0.9)	0	1 (0.5)	0	6 (0.8)	0
Weight increased	5 (0.9)	0	1 (0.5)	0	6 (0.8)	0	5 (0.9)	0	1 (0.5)	0	6 (0.8)	0
Adrenal insufficiency	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)
Anal incontinence	4 (0.8)	0	0	0	4 (0.5)	0	4 (0.8)	0	0	0	4 (0.5)	0
Atrial fibrillation	4 (0.8)	3 (0.6)	2 (1.0)	0	6 (0.8)	3 (0.4)	4 (0.8)	3 (0.6)	2 (1.0)	0	6 (0.8)	3 (0.4)
Bronchitis	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0
Candida infection	4 (0.8)	0	2 (1.0)	1 (0.5)	6 (0.8)	1 (0.1)	4 (0.8)	0	2 (1.0)	1 (0.5)	6 (0.8)	1 (0.1)
Cardiac failure congestive	4 (0.8)	3 (0.6)	1 (0.5)	0	5 (0.7)	3 (0.4)	4 (0.8)	3 (0.6)	1 (0.5)	0	5 (0.7)	3 (0.4)
Cellulitis	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)

Page 6 of 31

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Cognitive disorder	4 (0.8)	0	3 (1.5)	0	7 (1.0)	0	4 (0.8)	0	3 (1.5)	0	7 (1.0)	0
Decubitus ulcer	4 (0.8)	0	0	0	4 (0.5)	0	4 (0.8)	0	0	0	4 (0.5)	0
Delirium	4 (0.8)	0	1 (0.5)	1 (0.5)	5 (0.7)	1 (0.1)	4 (0.8)	0	1 (0.5)	1 (0.5)	5 (0.7)	1 (0.1)
Dental caries	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)
Herpes zoster	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)
Hyperphosphat aemia	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)
Hypothyroidism	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0
Infection	4 (0.8)	3 (0.6)	2 (1.0)	2 (1.0)	6 (0.8)	5 (0.7)	4 (0.8)	3 (0.6)	2 (1.0)	2 (1.0)	6 (0.8)	5 (0.7)
Influenza	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0
Joint swelling	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0
Ocular hyperaemia	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0
Oedema	4 (0.8)	0	3 (1.5)	0	7 (1.0)	0	4 (0.8)	0	3 (1.5)	0	7 (1.0)	0
Peripheral motor neuropathy	4 (0.8)	1 (0.2)	1 (0.5)	0	5 (0.7)	1 (0.1)	4 (0.8)	1 (0.2)	1 (0.5)	0	5 (0.7)	1 (0.1)
Peripheral sensorimotor neuropathy	4 (0.8)	0	0	0	4 (0.5)	0	4 (0.8)	0	0	0	4 (0.5)	0
Pruritus	4 (0.8)	0	0	0	4 (0.5)	0	4 (0.8)	0	0	0	4 (0.5)	0
Rhinorrhoea	4 (0.8)	0	0	0	4 (0.5)	0	4 (0.8)	0	0	0	4 (0.5)	0
Skin laceration	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0
Squamous cell carcinoma	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)
Subdural haematoma	4 (0.8)	4 (0.8)	2 (1.0)	2 (1.0)	6 (0.8)	6 (0.8)	4 (0.8)	4 (0.8)	2 (1.0)	2 (1.0)	6 (0.8)	6 (0.8)
Tooth infection	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0
Toothache*	3 (0.6)	0	0	0	3 (0.4)	0	4 (0.8)	1 (0.2)	0	0	4 (0.5)	1 (0.1)
Vitamin B12 deficiency	4 (0.8)	0	0	0	4 (0.5)	0	4 (0.8)	0	0	0	4 (0.5)	0
Wound	4 (0.8)	0	0	0	4 (0.5)	0	4 (0.8)	0	0	0	4 (0.5)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Balance disorder	3 (0.6)	0	2 (1.0)	0	5 (0.7)	0	3 (0.6)	0	2 (1.0)	0	5 (0.7)	0
Bladder spasm	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)
COVID-19	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)
Cardiac failure	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)
Chest discomfort	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Conjunctivitis	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Depressed mood	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Ear pain	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Eczema	3 (0.6)	0	2 (1.0)	0	5 (0.7)	0	3 (0.6)	0	2 (1.0)	0	5 (0.7)	0
Eye infection	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Facial paresis	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Haematochezia	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0
Hyperhidrosis	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Hyperuricaemia	3 (0.6)	2 (0.4)	1 (0.5)	0	4 (0.5)	2 (0.3)	3 (0.6)	2 (0.4)	1 (0.5)	0	4 (0.5)	2 (0.3)
Hypoesthesia oral	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0
Hypoglycaemia	3 (0.6)	1 (0.2)	1 (0.5)	0	4 (0.5)	1 (0.1)	3 (0.6)	1 (0.2)	1 (0.5)	0	4 (0.5)	1 (0.1)
Hypoxia	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Ischaemic stroke	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Lethargy	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Leukocytosis	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)
Lower respiratory tract infection	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Lymphoedema*	2 (0.4)	0	1 (0.5)	1 (0.5)	3 (0.4)	1 (0.1)	3 (0.6)	0	1 (0.5)	1 (0.5)	4 (0.5)	1 (0.1)
Micturition urgency	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0
Musculoskeletal pain	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Nephrolithiasis	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Non-cardiac chest pain*	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)
Orthostatic hypotension	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)
Pathological fracture	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Photophobia	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)
Presyncope	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Procedural pain	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Rash maculopapular	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Rectal haemorrhage*	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	3 (0.6)	1 (0.2)	1 (0.5)	0	4 (0.5)	1 (0.1)
Restless legs syndrome	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Rib fracture	3 (0.6)	0	3 (1.5)	1 (0.5)	6 (0.8)	1 (0.1)	3 (0.6)	0	3 (1.5)	1 (0.5)	6 (0.8)	1 (0.1)
Sinusitis	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0
Skin lesion	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Skin ulcer	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0
Swelling	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Testicular pain	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Thrombotic thrombocytopenic purpura	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)
Tooth abscess	3 (0.6)	1 (0.2)	1 (0.5)	0	4 (0.5)	1 (0.1)	3 (0.6)	1 (0.2)	1 (0.5)	0	4 (0.5)	1 (0.1)
Urosepsis	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)
Abscess limb	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Acidosis	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Alopecia	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Aphasia	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Appendicitis	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Appetite disorder	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Aptyalism	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0

Page 9 of 31

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Arrhythmia	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Bladder discomfort	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Blood blister	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Bradycardia	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Cachexia	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Cancer pain	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Cell death	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Conjunctival haemorrhage	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Defaecation urgency	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Dermal cyst	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Dermatitis	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Disease progression	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)
Disturbance in attention	2 (0.4)	0	3 (1.5)	0	5 (0.7)	0	2 (0.4)	0	3 (1.5)	0	5 (0.7)	0
Diverticulitis	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)
Dizziness postural	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Eccymosis	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Embolism	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Encephalopathy	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)
Eye inflammation	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Eye pain	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Eye pruritus	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Failure to thrive	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Febrile neutropenia	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Folate deficiency	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Foot fracture	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Gait disturbance	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Gastroenteritis	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
General physical health deterioration	2 (0.4)	1 (0.2)	3 (1.5)	3 (1.5)	5 (0.7)	4 (0.5)	2 (0.4)	1 (0.2)	3 (1.5)	3 (1.5)	5 (0.7)	4 (0.5)
Generalised oedema	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)
Haemoptysis	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Haemorrhage intracranial	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Haemorrhoids	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Hyperaesthesia	2 (0.4)	0	1 (0.5)	1 (0.5)	3 (0.4)	1 (0.1)	2 (0.4)	0	1 (0.5)	1 (0.5)	3 (0.4)	1 (0.1)
Hypernatraemia	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Ileus	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)
Infusion site extravasation	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Intervertebral disc protrusion	2 (0.4)	1 (0.2)	2 (1.0)	0	4 (0.5)	1 (0.1)	2 (0.4)	1 (0.2)	2 (1.0)	0	4 (0.5)	1 (0.1)
Irritability	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Joint injury	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Joint stiffness	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Kidney infection	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Lip dry	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Localised oedema*	1 (0.2)	0	0	0	1 (0.1)	0	2 (0.4)	0	0	0	2 (0.3)	0
Melaena	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Memory impairment	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Meniscus injury	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Metabolic encephalopathy	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)

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177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Metastases to central nervous system	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Metastases to meninges	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Mucosal inflammation	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Muscle strain	2 (0.4)	0	2 (1.0)	1 (0.5)	4 (0.5)	1 (0.1)	2 (0.4)	0	2 (1.0)	1 (0.5)	4 (0.5)	1 (0.1)
Nail infection	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Nasal dryness	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Nocturia	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Osteomyelitis	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Pelvic fracture	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Penile pain	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Perineal pain	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Peroneal nerve palsy	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Petechiae	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Proctalgia	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Radiculopathy	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Restlessness	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Scrotal oedema	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Seizure	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Septic shock	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Sneezing	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Somnolence	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Spinal fracture	2 (0.4)	2 (0.4)	1 (0.5)	0	3 (0.4)	2 (0.3)	2 (0.4)	2 (0.4)	1 (0.5)	0	3 (0.4)	2 (0.3)
Suprapubic pain	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Swelling face	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Throat irritation	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Tooth fracture	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Transient ischaemic attack	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Tremor	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Troponin I increased	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Tumour lysis syndrome	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Urine odour abnormal	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Ventricular tachycardia	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Vitamin B complex deficiency	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Wound infection	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Abdominal tenderness	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Abdominal wall wound	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Abscess jaw	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Accident at work	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Acetabulum fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Actinic keratosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Activated partial thromboplastin time prolonged	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Acute hepatic failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Acute respiratory failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Ageusia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Agitation	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Alanine aminotransferase decreased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Anaemia postoperative	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Anal injury	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Angina pectoris	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Anhedonia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Anosmia*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Anxiety disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Aortic stenosis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Aphthous ulcer	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Arachnoid cyst	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Arthritis	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0
Arthropod bite	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Axillary pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Bacteraemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bacterial sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Basal cell carcinoma	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Bell's palsy	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Benign prostatic hyperplasia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bicytopenia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bile duct stenosis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bladder obstruction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Bladder pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Blister	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Blood urea increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Blood urine present	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Bone cyst*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Bone loss	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Bone marrow failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bursitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cancer surgery	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Carbon dioxide decreased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cardiac flutter	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cardiomyopathy	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Catheter site bruise	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Catheter site pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cauda equina syndrome	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Cerebellar infarction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cerebral haemorrhage	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cerebral infarction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Chapped lips	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cholecystitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cholestasis	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Chondropathy	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Chromaturia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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Chronic obstructive pulmonary disease	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cirrhosis alcoholic	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Colon adenoma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Conjunctival oedema	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cranial nerve paralysis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cystitis bacterial	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cystitis noninfective	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cystitis radiation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Deafness	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Decreased activity	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dental restoration failure	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Depressive symptom	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dermatitis acneiform	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dermatitis bullous	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Device dislocation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Diabetes mellitus	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Diaphragmalgia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Diplopia	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Disseminated intravascular coagulation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Dry throat	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Duodenal ulcer	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Dupuytren's contracture	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dysphonia	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Ear disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Ear infection	1 (0.2)	0	3 (1.5)	0	4 (0.5)	0	1 (0.2)	0	3 (1.5)	0	4 (0.5)	0
Early satiety	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Enterococcal bacteraemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Enterocolitis infectious	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Erectile dysfunction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Erythema	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Escherichia sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Euthanasia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Exostosis of jaw	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Exposure to SARS-CoV-2	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Extradural abscess	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Extrasystoles	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Eye contusion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Eye discharge	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Eye injury	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Eye swelling	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Eyelid ptosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Facial pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Faeces discoloured	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Feeling abnormal	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Femoral neck fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Femur fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Flatulence	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Fluid retention	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Flushing	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Folliculitis	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Fungaemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Gastric haemorrhage	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Gastrointestinal motility disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Gastrointestinal pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Gastrointestinal stoma complication	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Genital pain	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Gingival bleeding	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Gingival pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Gingivitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Glaucoma	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Glossodynia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Gynaecomastia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Haematemesis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Head injury	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Heart rate increased	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Helicobacter infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hemiparesis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hepatic cytolysis	1 (0.2)	0	2 (1.0)	1 (0.5)	3 (0.4)	1 (0.1)	1 (0.2)	0	2 (1.0)	1 (0.5)	3 (0.4)	1 (0.1)
Hepatic encephalopathy	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hepatic failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hepatic lesion	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hepatitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Herpes virus infection	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Hiccups	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0
Hydroureter	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hyperchloraemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hypercholesterolaemia*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Hyperglobulinaemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hyperlipidaemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hypoglossal nerve paralysis	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Hypoproteinaemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Incontinence	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Infected dermal cyst	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Infusion related reaction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Inguinal hernia	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Injection site erythema	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Injection site reaction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Injection site swelling	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
International normalised ratio increased	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Intervertebral disc compression	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Intestinal obstruction*	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)
Intestinal perforation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Intestinal pseudo-obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Iron deficiency	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Jaundice	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Joint effusion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Joint range of motion decreased	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Klebsiella sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Lacrimation increased	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Large intestinal obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Libido increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Ligament sprain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Lip haematoma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Lip infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Lip pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Localised infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Loss of consciousness	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Lower gastrointestinal haemorrhage	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Lower limb fracture	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Lymph node pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Lymphadenopathy	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Macrocytosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Malignant melanoma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Malignant urinary tract obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Mallory-Weiss syndrome	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Melanocytic hyperplasia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Meniere's disease	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Meningism	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Metabolic acidosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Mixed anxiety and depressive disorder	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Multiple organ dysfunction syndrome	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Myocardial infarction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Myopathy	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Nail disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Neck dissection	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Neuralgia	1 (0.2)	0	3 (1.5)	0	4 (0.5)	0	1 (0.2)	0	3 (1.5)	0	4 (0.5)	0
Neuritis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Neuropathy peripheral	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Normocytic anaemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Oedema genital	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Oesophagitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Onychoclasia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Oral fungal infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Oral herpes	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Oral pain	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Oropharyngitis fungal	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Osteoarthritis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Osteolysis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Osteonecrosis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Osteopenia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Overdose	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pachymeningitis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pain management	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pain of skin	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pallor	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

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Palmar-plantar erythrodysesthesia syndrome	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Palpitations	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pancreatic carcinoma*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Paranasal sinus hyposecretion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Parotid gland enlargement	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Penile infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Periodontal disease	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Periorbital oedema	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Peripheral vascular disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Peripheral venous disease	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pneumonia aspiration	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pneumonitis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Poor quality sleep	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Post procedural fever	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Post procedural haematuria	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Proctitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Prostatitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Proteinuria	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Proteus infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Psoriasis	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0
Pulmonary fibrosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pulmonary oedema	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pulmonary pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Purpura	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pyelonephritis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pyelonephritis acute	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Rales	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Rash	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
erythematous												
Rash papular	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Renal colic	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Renal failure	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Renal haematoma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Renal pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Renal tubular acidosis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Respiratory distress	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Respiratory tract infection viral	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Retching	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Rhinitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Rosacea	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Rotator cuff syndrome	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
SARS-CoV-2 test positive*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Salivary duct obstruction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Salivary gland pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Scleral haemorrhage	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Secondary hypertension	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sensitive skin	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sensory disturbance	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sinus congestion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sinus headache	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sinus tachycardia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Skin atrophy	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Skin odour abnormal	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sleep apnoea syndrome	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Sleep disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Small intestinal obstruction	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Soft tissue infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Speech disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Squamous cell carcinoma of skin	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Staphylococcal bacteraemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Staphylococcus test positive	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Streptococcal bacteraemia*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Subcutaneous haematoma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Supraventricular extrasystoles	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Suspected COVID-19	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Swelling of eyelid	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Swollen tongue	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Synovitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Systemic inflammatory response syndrome	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tachycardia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Temperature intolerance	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Temporomandibular joint syndrome	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tendon injury	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tendonitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Thoracic vertebral fracture	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Tinea pedis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tinnitus	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Tongue discolouration	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Tongue fungal infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tongue geographic	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tooth disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tooth loss	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Torticollis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Trichoglossia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Trigger finger	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Troponin T increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tumour pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Umbilical hernia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Upper gastrointestinal haemorrhage	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Upper-airway cough syndrome	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Ureteral stent insertion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Ureteric obstruction	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Ureterocele	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Urethral pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Urethral stenosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Urge incontinence	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Urinary hesitation	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Urinary tract pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Urine analysis abnormal	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Urine output decreased	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Vascular malformation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Vertebral lesion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Viral infection	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Viral tonsillitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Vitamin B12 decreased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Vitamin D deficiency	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Vitreous floaters	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Xeroderma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Zinc deficiency	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Akinesia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Anaesthesia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Arteriosclerosis	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Biliary colic	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Blood iron decreased*	0	0	0	0	0	0	0	0	1 (0.5)	0	1 (0.1)	0
Brain oedema	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Burning sensation	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Cardio-respiratory arrest	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Cerebral haematoma	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Conjunctival hyperaemia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Deafness unilateral	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Dermatitis contact	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Diplegia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Embolism venous	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Erythema multiforme	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Extradural neoplasm	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Eye haematoma	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Facial paralysis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Fluid overload	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Gastrointestinal haemorrhage	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Haematoma	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Hallucination	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Hand fracture	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Heat stroke	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Hyperferritinæmia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Hypersensitivity	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Hypersomnia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Hypervolaemia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Hypophagia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Inappropriate antidiuretic hormone secretion	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Increased tendency to bruise	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Ingrowing nail	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Lactic acidosis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Lung disorder	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Lymphadenopathy	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
mediastinal												
Lymphangitis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Malnutrition	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Muscle atrophy	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Myopathy	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Neck mass	0	0	2 (1.0)	0	2 (0.3)	0	0	0	2 (1.0)	0	2 (0.3)	0
Oral infection	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Peritonitis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
bacterial												
Pharyngitis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pulmonary hypertension	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Pulmonary mass	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pulmonary valve disease	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Radiation skin injury	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Respiratory tract congestion	0	0	3 (1.5)	0	3 (0.4)	0	0	0	3 (1.5)	0	3 (0.4)	0
Seasonal allergy	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Sensorimotor disorder	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Skin abrasion	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Skin erosion	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Soft tissue injury	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Spinal cord disorder	0	0	2 (1.0)	1 (0.5)	2 (0.3)	1 (0.1)	0	0	2 (1.0)	1 (0.5)	2 (0.3)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Spinal stenosis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Squamous cell carcinoma of the tongue	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Streptococcal infection	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Supraventricular tachycardia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Thalamic infarction	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Transaminases increased	0	0	2 (1.0)	0	2 (0.3)	0	0	0	2 (1.0)	0	2 (0.3)	0
Volvulus	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Wound complication	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the Safety Update 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-1-3 2021-09-22 16:37

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-1-3s Study treatment-emergent adverse events by preferred term (Sub-study safety analysis set)

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	30 (100)	11 (36.7)
Nausea	11 (36.7)	0
Anaemia	9 (30.0)	4 (13.3)
Back pain	5 (16.7)	0
Dry mouth	5 (16.7)	0
Fatigue	5 (16.7)	1 (3.3)
Lymphopenia	5 (16.7)	1 (3.3)
Thrombocytopenia	4 (13.3)	2 (6.7)
Vomiting	4 (13.3)	0
Arthralgia	3 (10.0)	0
Blood creatinine increased	3 (10.0)	0
Bone pain	3 (10.0)	2 (6.7)
Diarrhoea	3 (10.0)	0
Dyspnoea	3 (10.0)	0
Leukopenia	3 (10.0)	2 (6.7)
Oedema peripheral	3 (10.0)	0
Pleural effusion	3 (10.0)	1 (3.3)
Urinary retention	3 (10.0)	1 (3.3)
Blood alkaline phosphatase increased	2 (6.7)	0
Cancer pain	2 (6.7)	1 (3.3)
Constipation	2 (6.7)	0
Cystitis	2 (6.7)	0
Decreased appetite	2 (6.7)	0
Extravasation	2 (6.7)	0
Flatulence	2 (6.7)	0
General physical health deterioration	2 (6.7)	1 (3.3)
Haematuria	2 (6.7)	0
Headache	2 (6.7)	0
Hyperuricaemia	2 (6.7)	0
Insomnia	2 (6.7)	0
Pain	2 (6.7)	1 (3.3)
Pain in extremity	2 (6.7)	1 (3.3)

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Pruritus	2 (6.7)	0
Pulmonary embolism	2 (6.7)	2 (6.7)
Pyrexia	2 (6.7)	0
Abdominal wall haematoma	1 (3.3)	0
Adrenal insufficiency	1 (3.3)	0
Ageusia	1 (3.3)	0
Agitation	1 (3.3)	0
Alanine aminotransferase increased	1 (3.3)	0
Angular cheilitis	1 (3.3)	0
Asthenia	1 (3.3)	1 (3.3)
Blood lactate dehydrogenase increased	1 (3.3)	0
C-reactive protein increased	1 (3.3)	0
Chills	1 (3.3)	0
Contusion	1 (3.3)	0
Decubitus ulcer	1 (3.3)	0
Dehydration	1 (3.3)	1 (3.3)
Depressed mood	1 (3.3)	0
Diverticulitis	1 (3.3)	0
Dizziness	1 (3.3)	0
Dyspepsia	1 (3.3)	0
Dysuria	1 (3.3)	0
End stage renal disease	1 (3.3)	1 (3.3)
Epistaxis	1 (3.3)	0
Fungal infection	1 (3.3)	0
Gastric ulcer	1 (3.3)	0
Generalised oedema	1 (3.3)	1 (3.3)
Gingivitis	1 (3.3)	0
Glomerular filtration rate decreased	1 (3.3)	0
Haematoma	1 (3.3)	0
Hyperkalaemia	1 (3.3)	0
Hypocalcaemia	1 (3.3)	0
Hypotension	1 (3.3)	0
Irritability	1 (3.3)	0
Loose tooth	1 (3.3)	0
Muscle spasms	1 (3.3)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Nail infection	1 (3.3)	0
Nervousness	1 (3.3)	0
Neuralgia	1 (3.3)	0
Oroantral fistula	1 (3.3)	0
Orthostatic intolerance	1 (3.3)	0
Osteonecrosis of jaw	1 (3.3)	0
Paraplegia	1 (3.3)	1 (3.3)
Polyneuropathy	1 (3.3)	0
Rash	1 (3.3)	0
Renal impairment	1 (3.3)	0
Restless legs syndrome	1 (3.3)	0
Rib fracture	1 (3.3)	0
Skin ulcer	1 (3.3)	0
Sleep disorder	1 (3.3)	0
Spinal pain	1 (3.3)	1 (3.3)
Spinal stenosis	1 (3.3)	1 (3.3)
Subcutaneous haematoma	1 (3.3)	0
Throat tightness	1 (3.3)	0
Toothache	1 (3.3)	0
Urinary tract infection	1 (3.3)	1 (3.3)
Urinary tract obstruction	1 (3.3)	0
Vaccination complication	1 (3.3)	0
Vertigo	1 (3.3)	0
Vitamin D deficiency	1 (3.3)	0
Weight decreased	1 (3.3)	0
Wound dehiscence	1 (3.3)	0

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-1-3s 2021-09-22 16:37

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Number of subjects with at least one event	519 (1415.7)	279 (91.1)	170 (1137.0)	78 (135.1)	689 (1335.0)	357 (98.1)	519 (1415.9)	281 (89.0)	170 (1137.0)	79 (135.4)	689 (1335.1)	360 (96.2)
Fatigue	228 (79.7)	31 (7.4)	47 (77.2)	3 (4.1)	275 (79.2)	34 (6.9)	228 (77.3)	31 (7.2)	47 (75.0)	3 (4.0)	275 (76.9)	34 (6.7)
Dry mouth	205 (75.1)	0	1 (1.4)	0	206 (59.7)	0	205 (73.1)	0	1 (1.4)	0	206 (58.1)	0
Nausea	187 (62.9)	7 (1.7)	34 (55.0)	1 (1.4)	221 (61.5)	8 (1.6)	188 (61.3)	7 (1.6)	34 (53.8)	1 (1.3)	222 (60.0)	8 (1.6)
Anaemia	168 (47.7)	68 (16.7)	27 (40.8)	10 (14.0)	195 (46.6)	78 (16.3)	168 (46.2)	68 (16.2)	27 (39.9)	10 (13.7)	195 (45.2)	78 (15.8)
Back pain	124 (34.0)	17 (4.0)	30 (44.7)	7 (9.7)	154 (35.7)	24 (4.8)	128 (34.2)	19 (4.3)	31 (45.1)	8 (10.9)	159 (35.9)	27 (5.3)
Arthralgia	118 (32.5)	6 (1.4)	26 (40.6)	1 (1.4)	144 (33.7)	7 (1.4)	120 (32.2)	6 (1.4)	26 (39.5)	1 (1.3)	146 (33.3)	7 (1.4)
Decreased appetite	112 (30.0)	10 (2.3)	30 (46.4)	1 (1.4)	142 (32.4)	11 (2.2)	113 (29.3)	10 (2.3)	30 (45.4)	1 (1.3)	143 (31.7)	11 (2.1)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Constipation	107 (29.3)	6 (1.4)	23 (33.6)	1 (1.4)	130 (30.0)	7 (1.4)	107 (28.4)	6 (1.4)	23 (32.7)	1 (1.3)	130 (29.0)	7 (1.4)
Diarrhoea	100 (27.5)	4 (0.9)	6 (8.5)	1 (1.4)	106 (24.4)	5 (1.0)	101 (27.0)	4 (0.9)	6 (8.3)	1 (1.3)	107 (24.0)	5 (1.0)
Vomiting	100 (26.8)	5 (1.2)	13 (18.5)	1 (1.4)	113 (25.5)	6 (1.2)	100 (25.9)	5 (1.1)	13 (18.1)	1 (1.3)	113 (24.7)	6 (1.2)
Thrombocytopenia	91 (23.0)	42 (10.0)	9 (12.6)	2 (2.8)	100 (21.4)	44 (8.9)	91 (22.2)	42 (9.7)	9 (12.3)	2 (2.7)	100 (20.7)	44 (8.7)
Lymphopenia	75 (19.6)	41 (10.2)	8 (11.3)	1 (1.4)	83 (18.3)	42 (8.8)	75 (19.0)	41 (9.9)	8 (11.1)	1 (1.3)	83 (17.8)	42 (8.6)
Leukopenia	66 (16.9)	13 (3.1)	4 (5.6)	1 (1.4)	70 (15.1)	14 (2.8)	66 (16.4)	13 (3.0)	4 (5.4)	1 (1.3)	70 (14.7)	14 (2.7)
Urinary tract infection	58 (14.6)	20 (4.8)	2 (2.8)	1 (1.4)	60 (12.7)	21 (4.3)	59 (14.3)	20 (4.6)	2 (2.7)	1 (1.3)	61 (12.6)	21 (4.1)
Bone pain	59 (14.8)	13 (3.1)	17 (24.5)	5 (6.9)	76 (16.2)	18 (3.6)	59 (14.3)	13 (3.0)	17 (23.9)	5 (6.8)	76 (15.7)	18 (3.5)
Weight decreased	57 (14.2)	2 (0.5)	18 (26.2)	0	75 (16.0)	2 (0.4)	58 (14.0)	2 (0.5)	20 (28.7)	1 (1.3)	78 (16.1)	3 (0.6)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Dyspnoea	53 (13.1)	7 (1.6)	20 (28.9)	3 (4.1)	73 (15.5)	10 (2.0)	53 (12.7)	8 (1.8)	20 (28.2)	3 (4.0)	73 (15.0)	11 (2.1)
Oedema	51 (12.7)	2 (0.5)	13 (19.6)	0	64 (13.7)	2 (0.4)	51 (12.4)	2 (0.5)	13 (19.3)	0	64 (13.3)	2 (0.4)
peripheral												
Pain in												
extremity												
Haematuria	45 (11.1)	13 (3.1)	9 (12.6)	1 (1.4)	54 (11.3)	14 (2.8)	45 (10.7)	13 (3.0)	9 (12.3)	1 (1.3)	54 (10.9)	14 (2.7)
Neutropenia	45 (11.1)	18 (4.3)	3 (4.2)	1 (1.4)	48 (10.0)	19 (3.8)	45 (10.7)	18 (4.1)	3 (4.1)	1 (1.3)	48 (9.7)	19 (3.7)
Dizziness	44 (10.9)	5 (1.2)	9 (13.2)	0	53 (11.3)	5 (1.0)	44 (10.6)	5 (1.1)	9 (13.0)	0	53 (10.9)	5 (1.0)
Cough	42 (10.4)	0	13 (18.8)	0	55 (11.6)	0	42 (10.1)	0	13 (18.3)	0	55 (11.3)	0
Hypokalaemia	40 (9.8)	5 (1.2)	8 (11.3)	0	48 (10.0)	5 (1.0)	40 (9.5)	5 (1.1)	8 (11.0)	0	48 (9.7)	5 (1.0)
Fall	38 (9.4)	1 (0.2)	12 (17.6)	2 (2.8)	50 (10.5)	3 (0.6)	39 (9.3)	1 (0.2)	12 (17.4)	2 (2.7)	51 (10.4)	3 (0.6)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Headache	37 (9.1)	4 (0.9)	4 (5.7)	0	41 (8.6)	4 (0.8)	37 (8.8)	4 (0.9)	4 (5.6)	0	41 (8.4)	4 (0.8)
Pyrexia	36 (8.7)	2 (0.5)	7 (9.8)	0	43 (8.9)	2 (0.4)	37 (8.7)	2 (0.5)	7 (9.6)	0	44 (8.8)	2 (0.4)
Hypocalcaemia	36 (8.8)	4 (0.9)	7 (9.9)	1 (1.4)	43 (8.9)	5 (1.0)	36 (8.5)	4 (0.9)	7 (9.7)	1 (1.3)	43 (8.7)	5 (1.0)
Asthenia	34 (8.3)	6 (1.4)	16 (23.7)	2 (2.8)	50 (10.5)	8 (1.6)	34 (8.0)	6 (1.4)	16 (23.1)	2 (2.7)	50 (10.2)	8 (1.6)
Pain	33 (8.0)	7 (1.6)	9 (12.7)	1 (1.4)	42 (8.7)	8 (1.6)	33 (7.8)	7 (1.6)	10 (13.8)	1 (1.3)	43 (8.7)	8 (1.5)
Abdominal pain	32 (7.7)	5 (1.2)	7 (9.9)	1 (1.4)	39 (8.1)	6 (1.2)	33 (7.7)	5 (1.1)	7 (9.7)	1 (1.3)	40 (8.0)	6 (1.2)
Hypertension	30 (7.3)	17 (4.0)	12 (17.7)	3 (4.2)	42 (8.8)	20 (4.1)	31 (7.3)	17 (3.9)	12 (17.3)	3 (4.1)	43 (8.7)	20 (3.9)
Hypophosphataemia	28 (6.8)	5 (1.2)	7 (9.8)	1 (1.4)	35 (7.3)	6 (1.2)	28 (6.6)	5 (1.1)	7 (9.6)	1 (1.3)	35 (7.0)	6 (1.2)
Blood creatinine increased	28 (6.8)	1 (0.2)	5 (6.9)	1 (1.4)	33 (6.8)	2 (0.4)	28 (6.6)	1 (0.2)	5 (6.8)	1 (1.3)	33 (6.6)	2 (0.4)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Insomnia	28 (6.7)	0	9 (12.8)	0	37 (7.6)	0	28 (6.5)	0	9 (12.5)	0	37 (7.4)	0
Muscular weakness	26 (6.2)	6 (1.4)	5 (7.0)	1 (1.4)	31 (6.4)	7 (1.4)	26 (6.0)	6 (1.4)	6 (8.2)	1 (1.3)	32 (6.3)	7 (1.4)
Dysgeusia	24 (5.8)	0	3 (4.2)	0	27 (5.6)	0	24 (5.6)	0	3 (4.1)	0	27 (5.4)	0
Hot flush	22 (5.4)	0	8 (11.5)	0	30 (6.3)	0	22 (5.3)	0	8 (11.2)	0	30 (6.1)	0
Aspartate aminotransferase increased	22 (5.3)	4 (0.9)	5 (7.0)	1 (1.4)	27 (5.5)	5 (1.0)	22 (5.1)	4 (0.9)	5 (6.8)	1 (1.3)	27 (5.4)	5 (1.0)
Dehydration	21 (5.0)	8 (1.9)	6 (8.4)	3 (4.1)	27 (5.5)	11 (2.2)	21 (4.9)	8 (1.8)	6 (8.2)	3 (4.0)	27 (5.4)	11 (2.1)
Hypoalbuminaemia	20 (4.8)	0	3 (4.1)	0	23 (4.7)	0	20 (4.6)	0	3 (4.0)	0	23 (4.5)	0
Hyponatraemia	20 (4.8)	1 (0.2)	9 (12.8)	3 (4.1)	29 (5.9)	4 (0.8)	20 (4.6)	1 (0.2)	9 (12.5)	3 (4.1)	29 (5.7)	4 (0.8)
Blood alkaline phosphatase increased	20 (4.7)	6 (1.4)	2 (2.8)	0	22 (4.4)	6 (1.2)	20 (4.6)	6 (1.4)	2 (2.7)	0	22 (4.3)	6 (1.2)

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MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

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Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

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	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Influenza like illness	19 (4.6)	0	1 (1.4)	0	20 (4.1)	0	19 (4.4)	0	1 (1.4)	0	20 (4.0)	0
Muscle spasms	19 (4.6)	0	4 (5.6)	0	23 (4.7)	0	19 (4.4)	0	4 (5.5)	0	23 (4.6)	0
Acute kidney injury	19 (4.5)	16 (3.8)	8 (11.2)	5 (6.9)	27 (5.5)	21 (4.2)	19 (4.3)	16 (3.6)	8 (11.0)	5 (6.8)	27 (5.3)	21 (4.1)
Myalgia	18 (4.4)	0	2 (2.8)	0	20 (4.1)	0	18 (4.2)	0	2 (2.7)	0	20 (4.0)	0
Peripheral sensory neuropathy	18 (4.3)	2 (0.5)	5 (7.2)	0	23 (4.7)	2 (0.4)	18 (4.2)	2 (0.5)	5 (7.1)	0	23 (4.6)	2 (0.4)
Nasopharyngitis	17 (4.1)	0	3 (4.1)	0	20 (4.1)	0	17 (4.0)	0	3 (4.1)	0	20 (4.0)	0
Musculoskeletal chest pain	17 (4.1)	0	7 (9.7)	1 (1.4)	24 (4.9)	1 (0.2)	17 (4.0)	0	7 (9.5)	1 (1.3)	24 (4.8)	1 (0.2)
Dyspepsia	17 (4.1)	0	1 (1.4)	0	18 (3.7)	0	17 (3.9)	0	1 (1.3)	0	18 (3.6)	0
Contusion	17 (4.1)	0	3 (4.2)	0	20 (4.1)	0	17 (3.9)	0	3 (4.1)	0	20 (4.0)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Hyperglycaemia	17 (4.1)	1 (0.2)	1 (1.4)	0	18 (3.7)	1 (0.2)	17 (3.9)	1 (0.2)	1 (1.3)	0	18 (3.6)	1 (0.2)
Abdominal pain upper	17 (4.1)	1 (0.2)	4 (5.5)	0	21 (4.3)	1 (0.2)	17 (3.9)	1 (0.2)	4 (5.4)	0	21 (4.1)	1 (0.2)
Hypotension	17 (4.0)	6 (1.4)	5 (7.0)	0	22 (4.5)	6 (1.2)	17 (3.9)	6 (1.4)	5 (6.8)	0	22 (4.3)	6 (1.2)
Dry eye	16 (3.8)	0	2 (2.8)	0	18 (3.7)	0	16 (3.7)	0	2 (2.7)	0	18 (3.6)	0
Flank pain	16 (3.8)	1 (0.2)	3 (4.2)	0	19 (3.9)	1 (0.2)	16 (3.7)	1 (0.2)	3 (4.1)	0	19 (3.7)	1 (0.2)
Neck pain	16 (3.8)	1 (0.2)	5 (7.2)	0	21 (4.3)	1 (0.2)	16 (3.7)	1 (0.2)	5 (7.1)	0	21 (4.1)	1 (0.2)
Rash	15 (3.6)	0	1 (1.4)	0	16 (3.3)	0	15 (3.5)	0	1 (1.3)	0	16 (3.2)	0
Alanine aminotransferase increased	15 (3.6)	2 (0.5)	6 (8.4)	2 (2.8)	21 (4.3)	4 (0.8)	15 (3.5)	2 (0.5)	6 (8.2)	2 (2.7)	21 (4.1)	4 (0.8)
Dysuria	14 (3.3)	2 (0.5)	2 (2.8)	0	16 (3.3)	2 (0.4)	14 (3.2)	2 (0.5)	2 (2.7)	0	16 (3.2)	2 (0.4)

Numbers (n) represent counts of subjects.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

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	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Pneumonia	14 (3.3)	8 (1.9)	6 (8.3)	2 (2.8)	20 (4.1)	10 (2.0)	14 (3.2)	8 (1.8)	6 (8.1)	2 (2.7)	20 (3.9)	10 (1.9)
Groin pain	14 (3.3)	2 (0.5)	1 (1.4)	0	15 (3.0)	2 (0.4)	14 (3.2)	2 (0.5)	1 (1.3)	0	15 (2.9)	2 (0.4)
Taste disorder	13 (3.1)	0	0	0	13 (2.6)	0	13 (3.0)	0	0	0	13 (2.6)	0
Hyperkalaemia	13 (3.1)	2 (0.5)	3 (4.2)	0	16 (3.2)	2 (0.4)	13 (3.0)	2 (0.5)	3 (4.1)	0	16 (3.1)	2 (0.4)
Malaise	13 (3.1)	1 (0.2)	1 (1.4)	0	14 (2.8)	1 (0.2)	13 (3.0)	1 (0.2)	1 (1.3)	0	14 (2.7)	1 (0.2)
Peripheral swelling	13 (3.1)	0	2 (2.8)	0	15 (3.0)	0	13 (3.0)	0	2 (2.7)	0	15 (2.9)	0
Urinary retention	13 (3.1)	5 (1.2)	4 (5.6)	1 (1.4)	17 (3.4)	6 (1.2)	13 (3.0)	5 (1.1)	4 (5.4)	1 (1.3)	17 (3.3)	6 (1.2)
Upper respiratory tract infection	12 (2.9)	0	1 (1.4)	0	13 (2.6)	0	12 (2.8)	0	1 (1.3)	0	13 (2.6)	0
Anxiety	11 (2.6)	1 (0.2)	5 (7.0)	0	16 (3.2)	1 (0.2)	12 (2.7)	1 (0.2)	5 (6.8)	0	17 (3.3)	1 (0.2)

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MedDRA version 24.0 and NCI CTCAE version 5.0.

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

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	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Blood lactate dehydrogenase increased	12 (2.8)	0	0	0	12 (2.4)	0	12 (2.7)	0	0	0	12 (2.3)	0
Confusional state	12 (2.8)	3 (0.7)	6 (8.3)	0	18 (3.6)	3 (0.6)	12 (2.7)	3 (0.7)	6 (8.1)	0	18 (3.5)	3 (0.6)
Paraesthesia	11 (2.6)	1 (0.2)	6 (8.4)	0	17 (3.5)	1 (0.2)	11 (2.5)	1 (0.2)	6 (8.2)	0	17 (3.3)	1 (0.2)
Vertigo	11 (2.6)	0	0	0	11 (2.2)	0	11 (2.5)	0	0	0	11 (2.2)	0
Depression	11 (2.6)	2 (0.5)	2 (2.8)	1 (1.4)	13 (2.6)	3 (0.6)	11 (2.5)	2 (0.5)	2 (2.7)	1 (1.3)	13 (2.5)	3 (0.6)
Dyspnoea exertional	11 (2.6)	0	2 (2.8)	0	13 (2.6)	0	11 (2.5)	0	2 (2.7)	0	13 (2.5)	0
Sepsis	11 (2.6)	10 (2.3)	3 (4.1)	3 (4.1)	14 (2.8)	13 (2.6)	11 (2.5)	10 (2.3)	3 (4.0)	3 (4.0)	14 (2.7)	13 (2.5)
Gastrooesophageal reflux disease	10 (2.4)	1 (0.2)	1 (1.4)	0	11 (2.2)	1 (0.2)	10 (2.3)	1 (0.2)	1 (1.3)	0	11 (2.2)	1 (0.2)
Pulmonary embolism	10 (2.4)	8 (1.9)	2 (2.8)	2 (2.8)	12 (2.4)	10 (2.0)	10 (2.3)	8 (1.8)	2 (2.7)	2 (2.7)	12 (2.4)	10 (2.0)

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177Lu-PSMA-617 SCS update

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	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Hypercalcaemia	10 (2.4)	1 (0.2)	4 (5.6)	0	14 (2.8)	1 (0.2)	10 (2.3)	1 (0.2)	4 (5.5)	0	14 (2.7)	1 (0.2)
Urinary incontinence	10 (2.4)	1 (0.2)	3 (4.2)	0	13 (2.6)	1 (0.2)	10 (2.3)	1 (0.2)	3 (4.1)	0	13 (2.5)	1 (0.2)
Hypoesthesia	10 (2.4)	0	3 (4.1)	0	13 (2.6)	0	10 (2.3)	0	3 (4.0)	0	13 (2.5)	0
Pollakiuria	9 (2.1)	0	7 (9.9)	0	16 (3.3)	0	9 (2.1)	0	7 (9.7)	0	16 (3.2)	0
Stomatitis	9 (2.1)	1 (0.2)	0	0	9 (1.8)	1 (0.2)	9 (2.1)	1 (0.2)	0	0	9 (1.8)	1 (0.2)
Pleural effusion	9 (2.1)	3 (0.7)	2 (2.8)	1 (1.4)	11 (2.2)	4 (0.8)	9 (2.1)	3 (0.7)	2 (2.7)	1 (1.3)	11 (2.1)	4 (0.8)
Vision blurred	9 (2.1)	2 (0.5)	2 (2.8)	0	11 (2.2)	2 (0.4)	9 (2.0)	2 (0.5)	2 (2.7)	0	11 (2.1)	2 (0.4)
Chest pain	9 (2.1)	0	0	0	9 (1.8)	0	9 (2.0)	0	0	0	9 (1.7)	0
Spinal compression fracture	8 (1.9)	2 (0.5)	1 (1.4)	0	9 (1.8)	2 (0.4)	8 (1.8)	2 (0.5)	1 (1.4)	0	9 (1.8)	2 (0.4)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Deep vein thrombosis	7 (1.6)	2 (0.5)	2 (2.8)	0	9 (1.8)	2 (0.4)	8 (1.8)	2 (0.5)	2 (2.7)	0	10 (2.0)	2 (0.4)
Limb injury	8 (1.9)	0	1 (1.4)	0	9 (1.8)	0	8 (1.8)	0	1 (1.3)	0	9 (1.8)	0
Pancytopenia	8 (1.9)	6 (1.4)	0	0	8 (1.6)	6 (1.2)	8 (1.8)	6 (1.4)	0	0	8 (1.6)	6 (1.2)
Hypomagnesae mia	8 (1.9)	0	0	0	8 (1.6)	0	8 (1.8)	0	0	0	8 (1.6)	0
Cataract	7 (1.7)	2 (0.5)	0	0	7 (1.4)	2 (0.4)	7 (1.6)	2 (0.5)	0	0	7 (1.4)	2 (0.4)
Nasal congestion	6 (1.4)	0	1 (1.4)	0	7 (1.4)	0	7 (1.6)	0	1 (1.3)	0	8 (1.6)	0
Musculoskeletal stiffness	7 (1.7)	0	0	0	7 (1.4)	0	7 (1.6)	0	0	0	7 (1.4)	0
Abdominal discomfort	7 (1.7)	0	1 (1.4)	0	8 (1.6)	0	7 (1.6)	0	1 (1.3)	0	8 (1.6)	0
Chills	7 (1.7)	0	2 (2.8)	0	9 (1.8)	0	7 (1.6)	0	2 (2.7)	0	9 (1.8)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Dry skin	7 (1.7)	0	2 (2.8)	0	9 (1.8)	0	7 (1.6)	0	2 (2.7)	0	9 (1.8)	0
Visual impairment	7 (1.6)	0	0	0	7 (1.4)	0	7 (1.6)	0	0	0	7 (1.4)	0
Hydronephrosis	7 (1.6)	3 (0.7)	1 (1.4)	1 (1.4)	8 (1.6)	4 (0.8)	7 (1.6)	3 (0.7)	1 (1.3)	1 (1.3)	8 (1.6)	4 (0.8)
Syncope	7 (1.6)	6 (1.4)	0	0	7 (1.4)	6 (1.2)	7 (1.6)	6 (1.4)	0	0	7 (1.4)	6 (1.2)
Dysphagia	7 (1.6)	0	2 (2.8)	0	9 (1.8)	0	7 (1.6)	0	2 (2.7)	0	9 (1.7)	0
Hyperbilirubinemia	7 (1.6)	3 (0.7)	3 (4.1)	1 (1.4)	10 (2.0)	4 (0.8)	7 (1.6)	3 (0.7)	3 (4.1)	1 (1.3)	10 (1.9)	4 (0.8)
Epistaxis	7 (1.6)	1 (0.2)	0	0	7 (1.4)	1 (0.2)	7 (1.6)	1 (0.2)	0	0	7 (1.4)	1 (0.2)
Spinal cord compression	7 (1.6)	7 (1.6)	11 (15.5)	11 (15.5)	18 (3.6)	18 (3.6)	7 (1.6)	7 (1.6)	12 (16.6)	12 (16.5)	19 (3.7)	19 (3.7)
Musculoskeletal discomfort	6 (1.4)	0	0	0	6 (1.2)	0	6 (1.4)	0	0	0	6 (1.2)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Oropharyngeal pain	6 (1.4)	0	0	0	6 (1.2)	0	6 (1.4)	0	0	0	6 (1.2)	0
Pain in jaw	6 (1.4)	0	2 (2.8)	0	8 (1.6)	0	6 (1.4)	0	2 (2.8)	0	8 (1.6)	0
Cystitis	6 (1.4)	1 (0.2)	0	0	6 (1.2)	1 (0.2)	6 (1.4)	1 (0.2)	0	0	6 (1.2)	1 (0.2)
Gout	6 (1.4)	1 (0.2)	0	0	6 (1.2)	1 (0.2)	6 (1.4)	1 (0.2)	0	0	6 (1.2)	1 (0.2)
Spinal pain	6 (1.4)	0	0	0	6 (1.2)	0	6 (1.4)	0	0	0	6 (1.2)	0
Abdominal distension	6 (1.4)	0	4 (5.6)	0	10 (2.0)	0	6 (1.4)	0	4 (5.4)	0	10 (1.9)	0
Osteonecrosis of jaw	4 (0.9)	0	1 (1.4)	1 (1.4)	5 (1.0)	1 (0.2)	6 (1.4)	0	1 (1.4)	1 (1.4)	7 (1.4)	1 (0.2)
Ascites	6 (1.4)	1 (0.2)	0	0	6 (1.2)	1 (0.2)	6 (1.4)	1 (0.2)	0	0	6 (1.2)	1 (0.2)
Urinary tract obstruction	6 (1.4)	5 (1.2)	0	0	6 (1.2)	5 (1.0)	6 (1.4)	5 (1.1)	0	0	6 (1.2)	5 (1.0)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Oral candidiasis	6 (1.4)	0	0	0	6 (1.2)	0	6 (1.4)	0	0	0	6 (1.2)	0
Weight increased	5 (1.2)	0	1 (1.4)	0	6 (1.2)	0	5 (1.1)	0	1 (1.3)	0	6 (1.2)	0
Sciatica	5 (1.2)	0	1 (1.4)	0	6 (1.2)	0	5 (1.1)	0	1 (1.3)	0	6 (1.2)	0
Coccydynia	5 (1.2)	0	0	0	5 (1.0)	0	5 (1.1)	0	0	0	5 (1.0)	0
Hip fracture	5 (1.2)	2 (0.5)	0	0	5 (1.0)	2 (0.4)	5 (1.1)	2 (0.5)	0	0	5 (1.0)	2 (0.4)
Night sweats	5 (1.2)	0	1 (1.4)	0	6 (1.2)	0	5 (1.1)	0	1 (1.4)	0	6 (1.2)	0
Gamma-glutamyltransferase increased	5 (1.2)	3 (0.7)	0	0	5 (1.0)	3 (0.6)	5 (1.1)	3 (0.7)	0	0	5 (1.0)	3 (0.6)
Productive cough	5 (1.2)	0	0	0	5 (1.0)	0	5 (1.1)	0	0	0	5 (1.0)	0
Pelvic pain	5 (1.2)	0	0	0	5 (1.0)	0	5 (1.1)	0	0	0	5 (1.0)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Abdominal pain lower	4 (0.9)	0	2 (2.8)	0	6 (1.2)	0	5 (1.1)	1 (0.2)	2 (2.7)	0	7 (1.4)	1 (0.2)
Chronic kidney disease	5 (1.2)	1 (0.2)	0	0	5 (1.0)	1 (0.2)	5 (1.1)	1 (0.2)	0	0	5 (1.0)	1 (0.2)
Mental status changes	5 (1.2)	3 (0.7)	0	0	5 (1.0)	3 (0.6)	5 (1.1)	3 (0.7)	0	0	5 (1.0)	3 (0.6)
Dysarthria	5 (1.2)	1 (0.2)	1 (1.4)	0	6 (1.2)	1 (0.2)	5 (1.1)	1 (0.2)	1 (1.3)	0	6 (1.2)	1 (0.2)
Rhinorrhoea	4 (0.9)	0	0	0	4 (0.8)	0	4 (0.9)	0	0	0	4 (0.8)	0
Dental caries	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)
Pruritus	4 (0.9)	0	0	0	4 (0.8)	0	4 (0.9)	0	0	0	4 (0.8)	0
Anal incontinence	4 (0.9)	0	0	0	4 (0.8)	0	4 (0.9)	0	0	0	4 (0.8)	0
Decubitus ulcer	4 (0.9)	0	0	0	4 (0.8)	0	4 (0.9)	0	0	0	4 (0.8)	0

Numbers (n) represent counts of subjects.

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Joint swelling	4 (0.9)	0	1 (1.4)	0	5 (1.0)	0	4 (0.9)	0	1 (1.3)	0	5 (1.0)	0
Ocular hyperaemia	4 (0.9)	0	1 (1.4)	0	5 (1.0)	0	4 (0.9)	0	1 (1.4)	0	5 (1.0)	0
Candida infection	4 (0.9)	0	2 (2.8)	1 (1.4)	6 (1.2)	1 (0.2)	4 (0.9)	0	2 (2.7)	1 (1.3)	6 (1.2)	1 (0.2)
Hypothyroidism	4 (0.9)	0	1 (1.4)	0	5 (1.0)	0	4 (0.9)	0	1 (1.3)	0	5 (1.0)	0
Toothache	3 (0.7)	0	0	0	3 (0.6)	0	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)
Cardiac failure	4 (0.9)	3 (0.7)	1 (1.4)	0	5 (1.0)	3 (0.6)	4 (0.9)	3 (0.7)	1 (1.3)	0	5 (1.0)	3 (0.6)
congestive												
Cognitive disorder	4 (0.9)	0	3 (4.2)	0	7 (1.4)	0	4 (0.9)	0	3 (4.1)	0	7 (1.4)	0
Peripheral sensorimotor neuropathy	4 (0.9)	0	0	0	4 (0.8)	0	4 (0.9)	0	0	0	4 (0.8)	0
Vitamin B12 deficiency	4 (0.9)	0	0	0	4 (0.8)	0	4 (0.9)	0	0	0	4 (0.8)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Bronchitis	4 (0.9)	0	2 (2.8)	0	6 (1.2)	0	4 (0.9)	0	2 (2.7)	0	6 (1.2)	0
Wound	4 (0.9)	0	0	0	4 (0.8)	0	4 (0.9)	0	0	0	4 (0.8)	0
Tooth infection	4 (0.9)	0	2 (2.8)	0	6 (1.2)	0	4 (0.9)	0	2 (2.7)	0	6 (1.2)	0
Cellulitis	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)
Squamous cell carcinoma	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)
Atrial fibrillation	4 (0.9)	3 (0.7)	2 (2.8)	0	6 (1.2)	3 (0.6)	4 (0.9)	3 (0.7)	2 (2.7)	0	6 (1.2)	3 (0.6)
Skin laceration	4 (0.9)	0	2 (2.8)	0	6 (1.2)	0	4 (0.9)	0	2 (2.7)	0	6 (1.2)	0
Peripheral motor neuropathy	4 (0.9)	1 (0.2)	1 (1.4)	0	5 (1.0)	1 (0.2)	4 (0.9)	1 (0.2)	1 (1.3)	0	5 (1.0)	1 (0.2)
Infection	4 (0.9)	3 (0.7)	2 (2.8)	2 (2.8)	6 (1.2)	5 (1.0)	4 (0.9)	3 (0.7)	2 (2.7)	2 (2.7)	6 (1.2)	5 (1.0)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Adrenal insufficiency	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)
Delirium	4 (0.9)	0	1 (1.4)	1 (1.4)	5 (1.0)	1 (0.2)	4 (0.9)	0	1 (1.3)	1 (1.3)	5 (1.0)	1 (0.2)
Hyperphosphatæmia	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)
Influenza	4 (0.9)	0	1 (1.4)	0	5 (1.0)	0	4 (0.9)	0	1 (1.4)	0	5 (1.0)	0
Herpes zoster	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)	4 (0.9)	1 (0.2)	0	0	4 (0.8)	1 (0.2)
Oedema	4 (0.9)	0	3 (4.1)	0	7 (1.4)	0	4 (0.9)	0	3 (4.1)	0	7 (1.4)	0
Subdural haematoma	4 (0.9)	4 (0.9)	2 (2.8)	2 (2.8)	6 (1.2)	6 (1.2)	4 (0.9)	4 (0.9)	2 (2.7)	2 (2.7)	6 (1.2)	6 (1.2)
Conjunctivitis	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Micturition urgency	3 (0.7)	0	1 (1.4)	0	4 (0.8)	0	3 (0.7)	0	1 (1.3)	0	4 (0.8)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Lethargy	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Procedural pain	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Ear pain	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Depressed mood	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Non-cardiac chest pain	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)
Restless legs syndrome	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Skin lesion	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Tooth abscess	3 (0.7)	1 (0.2)	1 (1.4)	0	4 (0.8)	1 (0.2)	3 (0.7)	1 (0.2)	1 (1.3)	0	4 (0.8)	1 (0.2)
Haematochezia	3 (0.7)	0	1 (1.4)	0	4 (0.8)	0	3 (0.7)	0	1 (1.3)	0	4 (0.8)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Hyperhidrosis	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Hypoglycaemia	3 (0.7)	1 (0.2)	1 (1.4)	0	4 (0.8)	1 (0.2)	3 (0.7)	1 (0.2)	1 (1.3)	0	4 (0.8)	1 (0.2)
Rash maculo-papular	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Rib fracture	3 (0.7)	0	3 (4.2)	1 (1.4)	6 (1.2)	1 (0.2)	3 (0.7)	0	3 (4.2)	1 (1.3)	6 (1.2)	1 (0.2)
Eczema	3 (0.7)	0	2 (2.8)	0	5 (1.0)	0	3 (0.7)	0	2 (2.7)	0	5 (1.0)	0
Eye infection	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Cardiac failure	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)
Musculoskeletal pain	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Testicular pain	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Orthostatic hypotension	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)
Lower respiratory tract infection	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
COVID-19	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)
Bladder spasm	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)
Lymphoedema	2 (0.5)	0	1 (1.4)	1 (1.4)	3 (0.6)	1 (0.2)	3 (0.7)	0	1 (1.3)	1 (1.3)	4 (0.8)	1 (0.2)
Urosepsis	3 (0.7)	3 (0.7)	0	0	3 (0.6)	3 (0.6)	3 (0.7)	3 (0.7)	0	0	3 (0.6)	3 (0.6)
Swelling	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Balance disorder	3 (0.7)	0	2 (2.8)	0	5 (1.0)	0	3 (0.7)	0	2 (2.7)	0	5 (1.0)	0
Skin ulcer	3 (0.7)	0	1 (1.4)	0	4 (0.8)	0	3 (0.7)	0	1 (1.3)	0	4 (0.8)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Chest discomfort	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Sinusitis	3 (0.7)	0	1 (1.4)	0	4 (0.8)	0	3 (0.7)	0	1 (1.3)	0	4 (0.8)	0
Leukocytosis	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)
Presyncope	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Hyperuricaemia	3 (0.7)	2 (0.5)	1 (1.4)	0	4 (0.8)	2 (0.4)	3 (0.7)	2 (0.5)	1 (1.3)	0	4 (0.8)	2 (0.4)
Photophobia	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)	3 (0.7)	1 (0.2)	0	0	3 (0.6)	1 (0.2)
Nephrolithiasis	3 (0.7)	2 (0.5)	0	0	3 (0.6)	2 (0.4)	3 (0.7)	2 (0.5)	0	0	3 (0.6)	2 (0.4)
Thrombotic thrombocytopenic purpura	3 (0.7)	3 (0.7)	0	0	3 (0.6)	3 (0.6)	3 (0.7)	3 (0.7)	0	0	3 (0.6)	3 (0.6)
Pathological fracture	3 (0.7)	2 (0.5)	0	0	3 (0.6)	2 (0.4)	3 (0.7)	2 (0.5)	0	0	3 (0.6)	2 (0.4)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Facial paresis	3 (0.7)	0	0	0	3 (0.6)	0	3 (0.7)	0	0	0	3 (0.6)	0
Hypoxia	3 (0.7)	2 (0.5)	0	0	3 (0.6)	2 (0.4)	3 (0.7)	2 (0.5)	0	0	3 (0.6)	2 (0.4)
Hypoesthesia oral	3 (0.7)	0	1 (1.4)	0	4 (0.8)	0	3 (0.7)	0	1 (1.3)	0	4 (0.8)	0
Ischaemic stroke	3 (0.7)	2 (0.5)	0	0	3 (0.6)	2 (0.4)	3 (0.7)	2 (0.5)	0	0	3 (0.6)	2 (0.4)
Rectal haemorrhage	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	3 (0.7)	1 (0.2)	1 (1.3)	0	4 (0.8)	1 (0.2)
Appendicitis	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)
Dermatitis	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Hyperaesthesia	2 (0.5)	0	1 (1.4)	1 (1.4)	3 (0.6)	1 (0.2)	2 (0.5)	0	1 (1.3)	1 (1.3)	3 (0.6)	1 (0.2)
Nasal dryness	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Foot fracture	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Dizziness	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
postural												
Swelling face	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Vitamin B complex deficiency	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Restlessness	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0
Eye pruritus	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Irritability	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Appetite disorder	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0
Seizure	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Meniscus injury	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Intervertebral disc protrusion	2 (0.5)	1 (0.2)	2 (2.8)	0	4 (0.8)	1 (0.2)	2 (0.5)	1 (0.2)	2 (2.7)	0	4 (0.8)	1 (0.2)
Ecchymosis	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0
Mucosal inflammation	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Somnolence	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Eye inflammation	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Wound infection	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Melaena	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Defaecation urgency	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Sneezing	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Conjunctival haemorrhage	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0
Blood blister	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Nail infection	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Perineal pain	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Osteomyelitis	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)
Arrhythmia	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Joint stiffness	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Aphasia	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Bladder discomfort	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Throat irritation	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Peroneal nerve palsy	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Alopecia	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Scrotal oedema	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Hypernatraemia	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0
Ileus	2 (0.5)	1 (0.2)	1 (1.4)	0	3 (0.6)	1 (0.2)	2 (0.5)	1 (0.2)	1 (1.3)	0	3 (0.6)	1 (0.2)
Abscess limb	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Infusion site extravasation	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0

Numbers (n) represent counts of subjects.

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Muscle strain	2 (0.5)	0	2 (2.8)	1 (1.4)	4 (0.8)	1 (0.2)	2 (0.5)	0	2 (2.7)	1 (1.3)	4 (0.8)	1 (0.2)
Memory impairment	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0
Bradycardia	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Diverticulitis	2 (0.5)	1 (0.2)	1 (1.4)	0	3 (0.6)	1 (0.2)	2 (0.5)	1 (0.2)	1 (1.3)	0	3 (0.6)	1 (0.2)
Spinal fracture	2 (0.5)	2 (0.5)	1 (1.4)	0	3 (0.6)	2 (0.4)	2 (0.5)	2 (0.5)	1 (1.3)	0	3 (0.6)	2 (0.4)
Folate deficiency	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Tooth fracture	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0
Gastroenteritis	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0
Urine odour abnormal	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0

Numbers (n) represent counts of subjects.

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Dermal cyst	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Suprapubic pain	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Proctalgia	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Lip dry	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0
Septic shock	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)
Failure to thrive	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)
Pelvic fracture	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Embolism	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)
Petechia	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Kidney infection	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Gait disturbance	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Disturbance in attention	2 (0.5)	0	3 (4.2)	0	5 (1.0)	0	2 (0.5)	0	3 (4.1)	0	5 (1.0)	0
Cachexia	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Aptyalism	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Eye pain	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Troponin I increased	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Haemorrhoids	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0
Nocturia	2 (0.5)	0	1 (1.4)	0	3 (0.6)	0	2 (0.5)	0	1 (1.3)	0	3 (0.6)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Penile pain	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Ventricular tachycardia	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Tumour lysis syndrome	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)
Localised oedema	1 (0.2)	0	0	0	1 (0.2)	0	2 (0.5)	0	0	0	2 (0.4)	0
Encephalopathy	2 (0.5)	2 (0.5)	1 (1.4)	1 (1.4)	3 (0.6)	3 (0.6)	2 (0.5)	2 (0.5)	1 (1.3)	1 (1.3)	3 (0.6)	3 (0.6)
Cell death	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Joint injury	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Cancer pain	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Transient ischaemic attack	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Haemoptysis	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Tremor	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Metastases to meninges	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
Radiculopathy	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)
Acidosis	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Generalised oedema	2 (0.5)	1 (0.2)	1 (1.4)	0	3 (0.6)	1 (0.2)	2 (0.5)	1 (0.2)	1 (1.3)	0	3 (0.6)	1 (0.2)
Metabolic encephalopathy	2 (0.5)	2 (0.5)	1 (1.4)	1 (1.4)	3 (0.6)	3 (0.6)	2 (0.5)	2 (0.5)	1 (1.3)	1 (1.3)	3 (0.6)	3 (0.6)
Metastases to central nervous system	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)	2 (0.5)	2 (0.5)	0	0	2 (0.4)	2 (0.4)
Disease progression	2 (0.5)	2 (0.5)	1 (1.4)	1 (1.4)	3 (0.6)	3 (0.6)	2 (0.5)	2 (0.5)	1 (1.3)	1 (1.3)	3 (0.6)	3 (0.6)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Haemorrhage	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)	2 (0.5)	1 (0.2)	0	0	2 (0.4)	1 (0.2)
intracranial												
General physical health deterioration	2 (0.5)	1 (0.2)	3 (4.1)	3 (4.1)	5 (1.0)	4 (0.8)	2 (0.5)	1 (0.2)	3 (4.0)	3 (4.0)	5 (1.0)	4 (0.8)
Febrile neutropenia	2 (0.5)	0	0	0	2 (0.4)	0	2 (0.5)	0	0	0	2 (0.4)	0
Ear infection	1 (0.2)	0	3 (4.2)	0	4 (0.8)	0	1 (0.2)	0	3 (4.1)	0	4 (0.8)	0
Injection site reaction	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Abdominal tenderness	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Anxiety disorder	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Incontinence	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Lymph node pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aepf-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Peripheral venous disease	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Vascular malformation	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Secondary hypertension	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Injection site swelling	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Bacterial sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Anaemia postoperative	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Thoracic vertebral fracture	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Sinus congestion	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Tongue discolouration	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Rhinitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Flatulence	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Glaucoma	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Lip pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Bursitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Anhedonia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Metabolic acidosis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Oesophagitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Dupuytren's contracture	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Carbon dioxide decreased	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Glossodynia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Psoriasis	1 (0.2)	0	2 (2.8)	0	3 (0.6)	0	1 (0.2)	0	2 (2.7)	0	3 (0.6)	0
Dermatitis acneiform	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Rotator cuff syndrome	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Femur fracture	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Chromaturia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Lower gastrointestinal haemorrhage	1 (0.2)	1 (0.2)	1 (1.4)	1 (1.4)	2 (0.4)	2 (0.4)	1 (0.2)	1 (0.2)	1 (1.3)	1 (1.3)	2 (0.4)	2 (0.4)
Upper-airway cough syndrome	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Pyelonephritis acute	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Rosacea	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Melanocytic hyperplasia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Salivary gland pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Lacrimation increased	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Intestinal obstruction	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	1 (1.3)	1 (1.3)	2 (0.4)	1 (0.2)
Folliculitis	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0
Parotid gland enlargement	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Actinic keratosis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Fungaemia	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Cardiomyopathy	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Vitreous floaters	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0
Mixed anxiety and depressive disorder	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Onychoclasia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Vitamin B12 decreased	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Cancer surgery	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Neuritis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Gingival pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Helicobacter infection	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Urinary hesitation	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Tendonitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Oral herpes	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Tooth loss	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Extradural abscess	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Hydroureter	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Ureterocele	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Accident at work	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Localised infection	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Tumour pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Eye injury	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Respiratory tract infection viral	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Hemiparesis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Bone loss	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Cystitis noninfective	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Dental restoration failure	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Scleral haemorrhage	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Chondropathy	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Subcutaneous haematoma	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Speech disorder	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Small intestinal obstruction	1 (0.2)	1 (0.2)	1 (1.4)	0	2 (0.4)	1 (0.2)	1 (0.2)	1 (0.2)	1 (1.3)	0	2 (0.4)	1 (0.2)
Libido increased	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Trichoglossia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Umbilical hernia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Rales	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Catheter site pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Pyelonephritis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Cerebellar infarction	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Pulmonary oedema	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Exostosis of jaw	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Nail disorder	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Upper gastrointestinal haemorrhage	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Anosmia	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.2)	0
Facial pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Meniere's disease	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Injection site erythema	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Neck dissection	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Hyperglobulinaemia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Iron deficiency	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Enterococcal bacteraemia	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Intervertebral disc compression	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
SARS-CoV-2 test positive	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.2)	0
Renal colic	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Infected dermal cyst	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Sinus headache	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Diabetes mellitus	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Ureteral stent insertion	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Chronic obstructive pulmonary disease	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Loss of consciousness	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Erectile dysfunction	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Pulmonary fibrosis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Eye discharge	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Paranasal sinus hyposecretion	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Osteoarthritis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Periodontal disease	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Gastrointestinal pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Skin atrophy	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Duodenal ulcer	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Squamous cell carcinoma of skin	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Axillary pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Gynaecomastia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Respiratory distress	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Malignant melanoma	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Blood urea increased	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Acetabulum fracture	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Anal injury	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Salivary duct obstruction	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Synovitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Supraventricular extrasystoles	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Femoral neck fracture	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Post procedural fever	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Post procedural haematuria	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Tachycardia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Temperature intolerance	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Zinc deficiency	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Hyperchloraemia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Hypoproteinaemia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Benign prostatic hyperplasia	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Sleep apnoea syndrome	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Faeces discoloured	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Eyelid ptosis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Fluid retention	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Tongue fungal infection	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Basal cell carcinoma	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0
Dysphonia	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Osteonecrosis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Sensory disturbance	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Angina pectoris	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Exposure to SARS-CoV-2	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Diplopia	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Neuropathy peripheral	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Pain of skin	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Skin odour abnormal	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Bone cyst	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.2)	0
Feeling abnormal	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Erythema	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Osteopenia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Streptococcal bacteraemia	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Arthritis	1 (0.2)	0	2 (2.8)	0	3 (0.6)	0	1 (0.2)	0	2 (2.7)	0	3 (0.6)	0
Cystitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
bacterial												
Macrocytosis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Rash	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
erythematous												
Diaphragmalgia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Suspected	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
COVID-19												
Oedema genital	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Decreased	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
activity												
Gastrointestinal	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
motility disorder												

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Overdose	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Cholecystitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Lower limb fracture	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Eye contusion	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Oral fungal infection	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Neuralgia	1 (0.2)	0	3 (4.2)	0	4 (0.8)	0	1 (0.2)	0	3 (4.1)	0	4 (0.8)	0
Renal failure	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Vertebral lesion	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Dry throat	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Retching	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Viral infection	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Palmar-plantar erythrodysesthesia syndrome	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Trigger finger	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0
Urinary tract pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Ligament sprain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Tooth disorder	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Colon adenoma	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Aortic stenosis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Heart rate increased	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Sleep disorder	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Abscess jaw	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Chapped lips	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Gastrointestinal stoma complication	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Purpura	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Blister	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Tinea pedis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Early satiety	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Lip infection	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Staphylococcus test positive	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Alanine aminotransferase decreased	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Lymphadenopathy	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Tendon injury	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Gingivitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Extrasystoles	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Flushing	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Xeroderma	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
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	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Tongue geographic	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Catheter site bruise	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Peripheral vascular disorder	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Temporomandibular joint syndrome	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Viral tonsillitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Meningism	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Joint effusion	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Tinnitus	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Ageusia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
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	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Hepatic lesion	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Cystitis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
radiation												
Cirrhosis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
alcoholic												
Joint range of motion	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0
decreased												
Malignant urinary tract obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Proteinuria	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Renal pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Conjunctival oedema	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Osteolysis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
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	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Hyperlipidaemia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Urethral pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Urethral stenosis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Urge incontinence	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Bladder obstruction	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Proteus infection	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Rash papular	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Bell's palsy	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Inguinal hernia	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Oral pain	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Pallor	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Lip haematoma	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Sensitive skin	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Dermatitis bullous	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Hypercholester olaemia	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.2)	0
Jaundice	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Penile infection	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Pneumonitis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Vitamin D deficiency	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Arachnoid cyst	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Bladder pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Activated partial thromboplastin time prolonged	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Proctitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Cerebral infarction	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Troponin T increased	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Genital pain	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Gastric haemorrhage	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Bone marrow failure	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Pulmonary pain	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Swollen tongue	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Cholestasis	1 (0.2)	1 (0.2)	1 (1.4)	1 (1.4)	2 (0.4)	2 (0.4)	1 (0.2)	1 (0.2)	1 (1.3)	1 (1.3)	2 (0.4)	2 (0.4)
Multiple organ dysfunction syndrome	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Cauda equina syndrome	1 (0.2)	1 (0.2)	1 (1.4)	1 (1.4)	2 (0.4)	2 (0.4)	1 (0.2)	1 (0.2)	1 (1.3)	1 (1.3)	2 (0.4)	2 (0.4)
Depressive symptom	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Pain management	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Sinus tachycardia	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Intestinal pseudo-obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Systemic inflammatory response syndrome	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Escherichia sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Palpitations	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Torticollis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Abdominal wall wound	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Disseminated intravascular coagulation	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Infusion related reaction	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Acute respiratory failure	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Ureteric obstruction	1 (0.2)	1 (0.2)	1 (1.4)	1 (1.4)	2 (0.4)	2 (0.4)	1 (0.2)	1 (0.2)	1 (1.3)	1 (1.3)	2 (0.4)	2 (0.4)
Pancreatic carcinoma	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Bacteraemia	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Device dislocation	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Poor quality sleep	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Cerebral haemorrhage	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Renal haematoma	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Aphthous ulcer	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Hepatic cytolysis	1 (0.2)	0	2 (2.8)	1 (1.4)	3 (0.6)	1 (0.2)	1 (0.2)	0	2 (2.7)	1 (1.3)	3 (0.6)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Hepatitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Blood urine present	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Cranial nerve paralysis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Hiccups	1 (0.2)	0	2 (2.8)	0	3 (0.6)	0	1 (0.2)	0	2 (2.7)	0	3 (0.6)	0
International normalised ratio increased	1 (0.2)	1 (0.2)	1 (1.4)	0	2 (0.4)	1 (0.2)	1 (0.2)	1 (0.2)	1 (1.3)	0	2 (0.4)	1 (0.2)
Urine analysis abnormal	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Pneumonia aspiration	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Bicytopenia	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Euthanasia	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Eye swelling	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Hepatic encephalopathy	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Myocardial infarction	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Myopathy	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Periorbital oedema	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Renal tubular acidosis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Swelling of eyelid	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Normocytic anaemia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Ear disorder	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

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MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Gingival bleeding	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Hypoglossal nerve paralysis	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.3)	0	2 (0.4)	0
Acute hepatic failure	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Bile duct stenosis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Arthropod bite	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Haematemesis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Prostatitis	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Mallory-Weiss syndrome	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Pachymeningitis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Soft tissue infection	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Agitation	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Cardiac flutter	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Urine output decreased	1 (0.2)	1 (0.2)	1 (1.4)	0	2 (0.4)	1 (0.2)	1 (0.2)	1 (0.2)	1 (1.3)	0	2 (0.4)	1 (0.2)
Staphylococcal bacteraemia	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Klebsiella sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Large intestinal obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Herpes virus infection	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0
Enterocolitis infectious	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Intestinal perforation	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Oropharyngitis fungal	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Deafness	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0	1 (0.2)	0	1 (1.4)	0	2 (0.4)	0
Head injury	1 (0.2)	0	0	0	1 (0.2)	0	1 (0.2)	0	0	0	1 (0.2)	0
Hepatic failure	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0	0	1 (0.2)	1 (0.2)
Aknesia	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Anaesthesia	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Arteriosclerosis	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Biliary colic	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Blood iron decreased	0	0	0	0	0	0	0	0	1 (1.3)	0	1 (0.2)	0
Brain oedema	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Burning sensation	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Cardio-respiratory arrest	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Cerebral haematoma	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Conjunctival hyperaemia	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Deafness unilateral	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.4)	0	1 (0.2)	0
Dermatitis contact	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Diplegia	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Embolism venous	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Erythema multiforme	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.4)	0	1 (0.2)	0
Extradural neoplasm	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Eye haematoma	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.4)	0	1 (0.2)	0
Facial paralysis	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Fluid overload	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Gastrointestinal haemorrhage	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)
Haematoma	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.4)	0	1 (0.2)	0
Hallucination	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Hand fracture	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Heat stroke	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Hyperferritinæmia	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Hypersensitivity	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.4)	0	1 (0.2)	0
Hypersomnia	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Hypervolaemia	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Hypophagia	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Inappropriate antidiuretic hormone secretion	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Increased tendency to bruise	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Ingrowing nail	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Lactic acidosis	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Lung disorder	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Lymphadenopathy mediastinal	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Lymphangitis	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Malnutrition	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Muscle atrophy	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Myelopathy	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Neck mass	0	0	2 (2.8)	0	2 (0.4)	0	0	0	2 (2.7)	0	2 (0.4)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Oral infection	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Peritonitis bacterial	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Pharyngitis	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Pulmonary hypertension	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Pulmonary mass	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Pulmonary valve disease	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Radiation skin injury	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Respiratory tract congestion	0	0	3 (4.1)	0	3 (0.6)	0	0	0	3 (4.0)	0	3 (0.6)	0
Seasonal allergy	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.4)	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Sensorimotor disorder	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Skin abrasion	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Skin erosion	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Soft tissue injury	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Spinal cord disorder	0	0	2 (2.8)	1 (1.4)	2 (0.4)	1 (0.2)	0	0	2 (2.7)	1 (1.3)	2 (0.4)	1 (0.2)
Spinal stenosis	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Squamous cell carcinoma of the tongue	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)
Streptococcal infection	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)
Supraventricular tachycardia	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.3)	1 (1.3)	1 (0.2)	1 (0.2)

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-4 Exposure-adjusted incidence rate of adverse events by preferred term and severity (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)	All grades n (IR per 100 STY)	Grade >=3 n (IR per 100 STY)
Thalamic infarction	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0
Transaminases increased	0	0	2 (2.8)	0	2 (0.4)	0	0	0	2 (2.7)	0	2 (0.4)	0
Volvulus	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)	0	0	1 (1.4)	1 (1.4)	1 (0.2)	1 (0.2)
Wound complication	0	0	1 (1.4)	0	1 (0.2)	0	0	0	1 (1.3)	0	1 (0.2)	0

Numbers (n) represent counts of subjects.

IR = exposure-adjusted incidence rate: number of subjects with an event divided by the corresponding sum of the exposure duration for all subjects, where duration of exposure in Subject Treatment Years (STY) is counted up to the first qualifying event (or end of time at risk for subjects without event).

MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: t-2-1-1-4 2021-09-22 16:39

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt-exadj.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-1-5 Randomized drug-related treatment-emergent adverse events by preferred term (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event*	451 (85.3)	150 (28.4)	59 (28.8)	8 (3.9)	510 (69.5)	158 (21.5)	451 (85.3)	151 (28.5)	59 (28.8)	8 (3.9)	510 (69.5)	159 (21.7)
Dry mouth	190 (35.9)	0	0	0	190 (25.9)	0	190 (35.9)	0	0	0	190 (25.9)	0
Fatigue	165 (31.2)	21 (4.0)	14 (6.8)	0	179 (24.4)	21 (2.9)	165 (31.2)	21 (4.0)	14 (6.8)	0	179 (24.4)	21 (2.9)
Nausea	148 (28.0)	5 (0.9)	8 (3.9)	0	156 (21.3)	5 (0.7)	148 (28.0)	5 (0.9)	8 (3.9)	0	156 (21.3)	5 (0.7)
Anaemia	135 (25.5)	51 (9.6)	6 (2.9)	1 (0.5)	141 (19.2)	52 (7.1)	135 (25.5)	51 (9.6)	6 (2.9)	1 (0.5)	141 (19.2)	52 (7.1)
Thrombocytopoenia	83 (15.7)	36 (6.8)	0	0	83 (11.3)	36 (4.9)	83 (15.7)	36 (6.8)	0	0	83 (11.3)	36 (4.9)
Decreased appetite	68 (12.9)	6 (1.1)	6 (2.9)	0	74 (10.1)	6 (0.8)	68 (12.9)	6 (1.1)	6 (2.9)	0	74 (10.1)	6 (0.8)
Vomiting	63 (11.9)	3 (0.6)	3 (1.5)	0	66 (9.0)	3 (0.4)	63 (11.9)	3 (0.6)	3 (1.5)	0	66 (9.0)	3 (0.4)
Lymphopenia	61 (11.5)	36 (6.8)	2 (1.0)	0	63 (8.6)	36 (4.9)	61 (11.5)	36 (6.8)	2 (1.0)	0	63 (8.6)	36 (4.9)
Diarrhoea	58 (11.0)	3 (0.6)	0	0	58 (7.9)	3 (0.4)	58 (11.0)	3 (0.6)	0	0	58 (7.9)	3 (0.4)
Leukopenia	58 (11.0)	12 (2.3)	3 (1.5)	0	61 (8.3)	12 (1.6)	58 (11.0)	12 (2.3)	3 (1.5)	0	61 (8.3)	12 (1.6)
Constipation*	45 (8.5)	2 (0.4)	1 (0.5)	0	46 (6.3)	2 (0.3)	46 (8.7)	3 (0.6)	1 (0.5)	0	47 (6.4)	3 (0.4)
Neutropenia	43 (8.1)	17 (3.2)	2 (1.0)	0	45 (6.1)	17 (2.3)	43 (8.1)	17 (3.2)	2 (1.0)	0	45 (6.1)	17 (2.3)
Arthralgia	25 (4.7)	2 (0.4)	2 (1.0)	0	27 (3.7)	2 (0.3)	25 (4.7)	2 (0.4)	2 (1.0)	0	27 (3.7)	2 (0.3)
Asthenia	24 (4.5)	3 (0.6)	10 (4.9)	0	34 (4.6)	3 (0.4)	24 (4.5)	3 (0.6)	10 (4.9)	0	34 (4.6)	3 (0.4)
Weight decreased	24 (4.5)	0	2 (1.0)	0	26 (3.5)	0	24 (4.5)	0	2 (1.0)	0	26 (3.5)	0
Bone pain	21 (4.0)	2 (0.4)	2 (1.0)	0	23 (3.1)	2 (0.3)	21 (4.0)	2 (0.4)	2 (1.0)	0	23 (3.1)	2 (0.3)
Dysgeusia	20 (3.8)	0	2 (1.0)	0	22 (3.0)	0	20 (3.8)	0	2 (1.0)	0	22 (3.0)	0
Hypokalaemia	15 (2.8)	4 (0.8)	2 (1.0)	0	17 (2.3)	4 (0.5)	15 (2.8)	4 (0.8)	2 (1.0)	0	17 (2.3)	4 (0.5)
Oedema peripheral	15 (2.8)	1 (0.2)	1 (0.5)	0	16 (2.2)	1 (0.1)	15 (2.8)	1 (0.2)	1 (0.5)	0	16 (2.2)	1 (0.1)
Back pain	14 (2.6)	2 (0.4)	0	0	14 (1.9)	2 (0.3)	14 (2.6)	2 (0.4)	0	0	14 (1.9)	2 (0.3)
Blood creatinine increased	14 (2.6)	0	0	0	14 (1.9)	0	14 (2.6)	0	0	0	14 (1.9)	0
Dizziness	13 (2.5)	0	2 (1.0)	0	15 (2.0)	0	13 (2.5)	0	2 (1.0)	0	15 (2.0)	0
Dry eye	13 (2.5)	0	1 (0.5)	0	14 (1.9)	0	13 (2.5)	0	1 (0.5)	0	14 (1.9)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Hypophosphataemia	12 (2.3)	3 (0.6)	1 (0.5)	1 (0.5)	13 (1.8)	4 (0.5)	12 (2.3)	3 (0.6)	1 (0.5)	1 (0.5)	13 (1.8)	4 (0.5)
Taste disorder	12 (2.3)	0	0	0	12 (1.6)	0	12 (2.3)	0	0	0	12 (1.6)	0
Dyspepsia	11 (2.1)	0	1 (0.5)	0	12 (1.6)	0	11 (2.1)	0	1 (0.5)	0	12 (1.6)	0
Headache	11 (2.1)	0	1 (0.5)	0	12 (1.6)	0	11 (2.1)	0	1 (0.5)	0	12 (1.6)	0
Pain	11 (2.1)	1 (0.2)	1 (0.5)	0	12 (1.6)	1 (0.1)	11 (2.1)	1 (0.2)	1 (0.5)	0	12 (1.6)	1 (0.1)
Dyspnoea	10 (1.9)	1 (0.2)	1 (0.5)	0	11 (1.5)	1 (0.1)	10 (1.9)	1 (0.2)	1 (0.5)	0	11 (1.5)	1 (0.1)
Abdominal pain upper	9 (1.7)	0	1 (0.5)	0	10 (1.4)	0	9 (1.7)	0	1 (0.5)	0	10 (1.4)	0
Malaise	9 (1.7)	1 (0.2)	1 (0.5)	0	10 (1.4)	1 (0.1)	9 (1.7)	1 (0.2)	1 (0.5)	0	10 (1.4)	1 (0.1)
Myalgia	9 (1.7)	0	1 (0.5)	0	10 (1.4)	0	9 (1.7)	0	1 (0.5)	0	10 (1.4)	0
Abdominal pain	8 (1.5)	1 (0.2)	1 (0.5)	0	9 (1.2)	1 (0.1)	8 (1.5)	1 (0.2)	1 (0.5)	0	9 (1.2)	1 (0.1)
Aspartate aminotransferase increased	8 (1.5)	0	3 (1.5)	1 (0.5)	11 (1.5)	1 (0.1)	8 (1.5)	0	3 (1.5)	1 (0.5)	11 (1.5)	1 (0.1)
Hypercalcaemia	8 (1.5)	1 (0.2)	2 (1.0)	0	10 (1.4)	1 (0.1)	8 (1.5)	1 (0.2)	2 (1.0)	0	10 (1.4)	1 (0.1)
Hypocalcaemia	8 (1.5)	1 (0.2)	0	0	8 (1.1)	1 (0.1)	8 (1.5)	1 (0.2)	0	0	8 (1.1)	1 (0.1)
Hyponatraemia	8 (1.5)	0	0	0	8 (1.1)	0	8 (1.5)	0	0	0	8 (1.1)	0
Alanine aminotransferase increased	7 (1.3)	1 (0.2)	4 (2.0)	1 (0.5)	11 (1.5)	2 (0.3)	7 (1.3)	1 (0.2)	4 (2.0)	1 (0.5)	11 (1.5)	2 (0.3)
Blood alkaline phosphatase increased	7 (1.3)	2 (0.4)	1 (0.5)	0	8 (1.1)	2 (0.3)	7 (1.3)	2 (0.4)	1 (0.5)	0	8 (1.1)	2 (0.3)
Haematuria	7 (1.3)	2 (0.4)	1 (0.5)	0	8 (1.1)	2 (0.3)	7 (1.3)	2 (0.4)	1 (0.5)	0	8 (1.1)	2 (0.3)
Hot flush	7 (1.3)	0	4 (2.0)	0	11 (1.5)	0	7 (1.3)	0	4 (2.0)	0	11 (1.5)	0
Hypertension	7 (1.3)	5 (0.9)	2 (1.0)	1 (0.5)	9 (1.2)	6 (0.8)	7 (1.3)	5 (0.9)	2 (1.0)	1 (0.5)	9 (1.2)	6 (0.8)
Hyperglycaemia	6 (1.1)	0	0	0	6 (0.8)	0	6 (1.1)	0	0	0	6 (0.8)	0
Hyperkalaemia	6 (1.1)	0	1 (0.5)	0	7 (1.0)	0	6 (1.1)	0	1 (0.5)	0	7 (1.0)	0
Muscular weakness	6 (1.1)	2 (0.4)	0	0	6 (0.8)	2 (0.3)	6 (1.1)	2 (0.4)	0	0	6 (0.8)	2 (0.3)
Pancytopenia	6 (1.1)	5 (0.9)	0	0	6 (0.8)	5 (0.7)	6 (1.1)	5 (0.9)	0	0	6 (0.8)	5 (0.7)
Stomatitis	6 (1.1)	0	0	0	6 (0.8)	0	6 (1.1)	0	0	0	6 (0.8)	0
Insomnia	5 (0.9)	0	0	0	5 (0.7)	0	5 (0.9)	0	0	0	5 (0.7)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Pain in extremity	5 (0.9)	0	0	0	5 (0.7)	0	5 (0.9)	0	0	0	5 (0.7)	0
Acute kidney injury	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)
Cough	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0
Dehydration	4 (0.8)	2 (0.4)	0	0	4 (0.5)	2 (0.3)	4 (0.8)	2 (0.4)	0	0	4 (0.5)	2 (0.3)
Dry skin	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0
Epistaxis	4 (0.8)	0	0	0	4 (0.5)	0	4 (0.8)	0	0	0	4 (0.5)	0
Fall	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0
Hypoalbuminemia	4 (0.8)	0	0	0	4 (0.5)	0	4 (0.8)	0	0	0	4 (0.5)	0
Muscle spasms	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0
Pneumonia	4 (0.8)	2 (0.4)	0	0	4 (0.5)	2 (0.3)	4 (0.8)	2 (0.4)	0	0	4 (0.5)	2 (0.3)
Pyrexia	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0
Urinary tract infection	4 (0.8)	2 (0.4)	0	0	4 (0.5)	2 (0.3)	4 (0.8)	2 (0.4)	0	0	4 (0.5)	2 (0.3)
Abdominal discomfort	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Candida infection	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Confusional state*	2 (0.4)	0	2 (1.0)	0	4 (0.5)	0	3 (0.6)	1 (0.2)	2 (1.0)	0	5 (0.7)	1 (0.1)
Contusion	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0
Groin pain	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)
Influenza like illness	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Joint swelling	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Oral candidiasis	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Peripheral sensory neuropathy	3 (0.6)	0	3 (1.5)	0	6 (0.8)	0	3 (0.6)	0	3 (1.5)	0	6 (0.8)	0
Rash	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Swelling	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0

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177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Thrombotic thrombocytopenic purpura	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)
Anal incontinence	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Appetite disorder	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Aptyalism	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Blood lactate dehydrogenase increased	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Chills	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Deep vein thrombosis	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Delirium	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Dental caries	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Dysphagia	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Dyspnoea exertional	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Facial paresis	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Gamma-glutamyltransferase increased	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Gastrooesophageal reflux disease	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Generalised oedema	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Haemorrhage intracranial	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Herpes zoster	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Hip fracture*	1 (0.2)	0	0	0	1 (0.1)	0	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Joint stiffness	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Musculoskeletal chest pain	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Musculoskeletal discomfort	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Oropharyngeal pain	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Peripheral swelling	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Petechia	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Pruritus	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Testicular pain	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Tumour lysis syndrome	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Urinary retention	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Visual impairment	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Abdominal distension	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Acidosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Adrenal insufficiency	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Ageusia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Alanine aminotransferase decreased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Alopecia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Arthritis	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Ascites	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Balance disorder	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0
Bicytopenia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Blood urea increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Blood urine present	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Bone marrow failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cardiac failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cell death	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cerebral infarction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Chapped lips	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Chest discomfort	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Chronic kidney disease	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cognitive disorder	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0
Conjunctival haemorrhage	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dermatitis acneiform	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Disturbance in attention	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Dry throat	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dysuria	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Early satiety	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Encephalopathy	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Erythema	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Eye pruritus	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Febrile neutropenia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Flank pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Fluid retention	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Flushing	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Folliculitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Gastric haemorrhage*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Gastrointestinal pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Gingival bleeding	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Gingival pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Gynaecomastia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Haemorrhoids	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Heart rate increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hepatic cytolysis	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Hyperbilirubinaemia	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)
Hyperchloraemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hyperhidrosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hyperphosphataemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hyperuricaemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hypoesthesia oral	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hypomagnesae mia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hypotension	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hypothyroidism	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hypoxia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Infection	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Injection site reaction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Lethargy	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Lip dry	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Lip pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Localised oedema	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Lymphoedema	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Melaena	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Meningism	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Mucosal inflammation	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Musculoskeletal stiffness	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Nasal congestion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Nasal dryness	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Nasopharyngitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Neck pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Oesophagitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Oral fungal infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Osteoarthritis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Osteonecrosis of jaw*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Pain in jaw	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pain of skin	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Palmar-plantar erythrodysesthesia syndrome	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Paraesthesia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Paranasal sinus hyposecretion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Parotid gland enlargement	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pathological fracture	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pelvic fracture	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pelvic pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Periodontal disease	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Peripheral sensorimotor neuropathy	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Photophobia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pollakiuria	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Presyncope	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Procedural pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Proteinuria	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pulmonary embolism	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Rash maculo-papular	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Rash papular	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Restlessness	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Rhinorrhoea	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Salivary duct obstruction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Salivary gland pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sciatica	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Seizure	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Septic shock	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Sinus headache	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sinus tachycardia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Skin odour abnormal	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Sneezing	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Somnolence	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Spinal compression fracture	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Spinal pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Squamous cell carcinoma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Subcutaneous haematoma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Subdural haematoma	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Supraventricular extrasystoles	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Swelling face	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Swollen tongue	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Syncope	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Temporomandibular joint syndrome	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Throat irritation	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tongue discolouration	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tongue fungal infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tooth infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Transient ischaemic attack	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tumour pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Upper gastrointestinal haemorrhage	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Upper respiratory tract infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Upper-airway cough syndrome	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Urinary tract obstruction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Urinary tract pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Urine analysis abnormal	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Ventricular tachycardia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Vertebral lesion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Vertigo	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Vision blurred	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Vitamin B complex deficiency	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Weight increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Wound infection	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Xeroderma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Abdominal pain lower	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Anxiety	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Deafness	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Flatulence	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Hypernatraemia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Hypervolaemia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Inappropriate antidiuretic hormone secretion	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Lacrimation increased	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Lower gastrointestinal haemorrhage	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Memory impairment	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Oedema	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Peripheral motor neuropathy	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Spinal cord compression	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Transaminases increased	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Urinary incontinence	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the Safety Update 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-1-5 2021-09-22 16:37

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-1-5s Study drug-related treatment-emergent adverse events by preferred term (Sub-study safety analysis set)

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	19 (63.3)	6 (20.0)
Anaemia	7 (23.3)	2 (6.7)
Nausea	7 (23.3)	0
Dry mouth	4 (13.3)	0
Lymphopenia	4 (13.3)	0
Blood creatinine increased	3 (10.0)	0
Fatigue	3 (10.0)	1 (3.3)
Thrombocytopenia	3 (10.0)	2 (6.7)
Vomiting	3 (10.0)	0
Decreased appetite	2 (6.7)	0
Leukopenia	2 (6.7)	1 (3.3)
Ageusia	1 (3.3)	0
Agitation	1 (3.3)	0
Arthralgia	1 (3.3)	0
Asthenia	1 (3.3)	1 (3.3)
Back pain	1 (3.3)	0
Blood alkaline phosphatase increased	1 (3.3)	0
Diarrhoea	1 (3.3)	0
Dizziness	1 (3.3)	0
General physical health deterioration	1 (3.3)	0
Glomerular filtration rate decreased	1 (3.3)	0
Irritability	1 (3.3)	0
Pruritus	1 (3.3)	0
Urinary retention	1 (3.3)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)

All grades	Grade >=3
n (%)	n (%)

Preferred term

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-1-5s 2021-09-22 16:37

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-1-6 Overview of adverse events during long-term follow-up (FAS safety set)

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
AE*	123 (23.3)	53 (25.9)	176 (24.0)	136 (25.7)	54 (26.3)	190 (25.9)
Grade 3/4/5 AE*	61 (11.5)	29 (14.1)	90 (12.3)	65 (12.3)	30 (14.6)	95 (12.9)
Fatal AE*	7 (1.3)	7 (3.4)	14 (1.9)	10 (1.9)	7 (3.4)	17 (2.3)

Adverse event (AE) during long-term follow-up = an AE that was reported during the long-term follow-up period after discontinuation of study treatment.

A patient with multiple grades for an AE is only counted under the maximum grade.

Fatal AE is any Grade 5 AE.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-1-6 2021-09-22 16:44

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-1-7 Adverse events during long-term follow-up by preferred term (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event*	123 (23.3)	61 (11.5)	53 (25.9)	29 (14.1)	176 (24.0)	90 (12.3)	136 (25.7)	65 (12.3)	54 (26.3)	30 (14.6)	190 (25.9)	95 (12.9)
Fatigue*	37 (7.0)	6 (1.1)	14 (6.8)	2 (1.0)	51 (6.9)	8 (1.1)	41 (7.8)	7 (1.3)	15 (7.3)	2 (1.0)	56 (7.6)	9 (1.2)
Anaemia*	34 (6.4)	14 (2.6)	15 (7.3)	8 (3.9)	49 (6.7)	22 (3.0)	35 (6.6)	14 (2.6)	15 (7.3)	8 (3.9)	50 (6.8)	22 (3.0)
Nausea*	20 (3.8)	1 (0.2)	13 (6.3)	0	33 (4.5)	1 (0.1)	21 (4.0)	1 (0.2)	14 (6.8)	0	35 (4.8)	1 (0.1)
Thrombocytopoenia*	18 (3.4)	11 (2.1)	9 (4.4)	5 (2.4)	27 (3.7)	16 (2.2)	19 (3.6)	12 (2.3)	9 (4.4)	5 (2.4)	28 (3.8)	17 (2.3)
Back pain*	14 (2.6)	2 (0.4)	8 (3.9)	1 (0.5)	22 (3.0)	3 (0.4)	16 (3.0)	3 (0.6)	8 (3.9)	1 (0.5)	24 (3.3)	4 (0.5)
Arthralgia*	13 (2.5)	1 (0.2)	4 (2.0)	1 (0.5)	17 (2.3)	2 (0.3)	14 (2.6)	1 (0.2)	5 (2.4)	1 (0.5)	19 (2.6)	2 (0.3)
Asthenia*	12 (2.3)	1 (0.2)	9 (4.4)	0	21 (2.9)	1 (0.1)	13 (2.5)	1 (0.2)	9 (4.4)	0	22 (3.0)	1 (0.1)
Diarrhoea*	11 (2.1)	1 (0.2)	2 (1.0)	0	13 (1.8)	1 (0.1)	13 (2.5)	1 (0.2)	3 (1.5)	0	16 (2.2)	1 (0.1)
Oedema peripheral*	10 (1.9)	0	5 (2.4)	0	15 (2.0)	0	13 (2.5)	0	6 (2.9)	0	19 (2.6)	0
Pain*	9 (1.7)	2 (0.4)	3 (1.5)	0	12 (1.6)	2 (0.3)	12 (2.3)	2 (0.4)	3 (1.5)	0	15 (2.0)	2 (0.3)
Decreased appetite*	11 (2.1)	1 (0.2)	8 (3.9)	1 (0.5)	19 (2.6)	2 (0.3)	11 (2.1)	1 (0.2)	9 (4.4)	1 (0.5)	20 (2.7)	2 (0.3)
Vomiting*	11 (2.1)	2 (0.4)	6 (2.9)	0	17 (2.3)	2 (0.3)	11 (2.1)	2 (0.4)	7 (3.4)	0	18 (2.5)	2 (0.3)
Bone pain*	9 (1.7)	2 (0.4)	6 (2.9)	1 (0.5)	15 (2.0)	3 (0.4)	10 (1.9)	2 (0.4)	7 (3.4)	1 (0.5)	17 (2.3)	3 (0.4)
Constipation*	8 (1.5)	0	5 (2.4)	0	13 (1.8)	0	10 (1.9)	0	6 (2.9)	0	16 (2.2)	0
Dyspnoea*	7 (1.3)	0	5 (2.4)	1 (0.5)	12 (1.6)	1 (0.1)	8 (1.5)	0	5 (2.4)	1 (0.5)	13 (1.8)	1 (0.1)
Haematuria*	5 (0.9)	0	6 (2.9)	0	11 (1.5)	0	8 (1.5)	1 (0.2)	8 (3.9)	0	16 (2.2)	1 (0.1)
Peripheral sensory neuropathy*	7 (1.3)	0	1 (0.5)	0	8 (1.1)	0	8 (1.5)	0	1 (0.5)	0	9 (1.2)	0
Tachycardia*	6 (1.1)	0	0	0	6 (0.8)	0	8 (1.5)	0	0	0	8 (1.1)	0
Lymphopenia	7 (1.3)	1 (0.2)	1 (0.5)	1 (0.5)	8 (1.1)	2 (0.3)	7 (1.3)	1 (0.2)	1 (0.5)	1 (0.5)	8 (1.1)	2 (0.3)
Urinary tract infection*	4 (0.8)	1 (0.2)	2 (1.0)	1 (0.5)	6 (0.8)	2 (0.3)	7 (1.3)	2 (0.4)	3 (1.5)	1 (0.5)	10 (1.4)	3 (0.4)
Weight decreased*	4 (0.8)	1 (0.2)	4 (2.0)	0	8 (1.1)	1 (0.1)	7 (1.3)	1 (0.2)	6 (2.9)	1 (0.5)	13 (1.8)	2 (0.3)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Neutropenia*	4 (0.8)	2 (0.4)	2 (1.0)	1 (0.5)	6 (0.8)	3 (0.4)	6 (1.1)	2 (0.4)	2 (1.0)	1 (0.5)	8 (1.1)	3 (0.4)
Pyrexia*	4 (0.8)	1 (0.2)	3 (1.5)	1 (0.5)	7 (1.0)	2 (0.3)	6 (1.1)	2 (0.4)	3 (1.5)	1 (0.5)	9 (1.2)	3 (0.4)
Deep vein thrombosis*	2 (0.4)	0	0	0	2 (0.3)	0	5 (0.9)	1 (0.2)	0	0	5 (0.7)	1 (0.1)
Epistaxis*	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0	5 (0.9)	0	2 (1.0)	0	7 (1.0)	0
Insomnia	5 (0.9)	0	1 (0.5)	0	6 (0.8)	0	5 (0.9)	0	1 (0.5)	0	6 (0.8)	0
Pain in extremity	5 (0.9)	0	2 (1.0)	0	7 (1.0)	0	5 (0.9)	0	2 (1.0)	0	7 (1.0)	0
Abdominal pain*	4 (0.8)	1 (0.2)	1 (0.5)	0	5 (0.7)	1 (0.1)	4 (0.8)	1 (0.2)	3 (1.5)	0	7 (1.0)	1 (0.1)
Depression	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0	4 (0.8)	0	2 (1.0)	0	6 (0.8)	0
Headache	4 (0.8)	0	4 (2.0)	0	8 (1.1)	0	4 (0.8)	0	4 (2.0)	0	8 (1.1)	0
Hyponatraemia	4 (0.8)	3 (0.6)	0	0	4 (0.5)	3 (0.4)	4 (0.8)	3 (0.6)	0	0	4 (0.5)	3 (0.4)
Pancytopenia	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)
Rash	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0	4 (0.8)	0	1 (0.5)	0	5 (0.7)	0
Acute kidney injury*	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Chest pain	3 (0.6)	2 (0.4)	1 (0.5)	0	4 (0.5)	2 (0.3)	3 (0.6)	2 (0.4)	1 (0.5)	0	4 (0.5)	2 (0.3)
Dehydration*	2 (0.4)	0	0	0	2 (0.3)	0	3 (0.6)	0	0	0	3 (0.4)	0
Fall*	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	3 (0.6)	1 (0.2)	1 (0.5)	0	4 (0.5)	1 (0.1)
Flank pain	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0
General physical health deterioration*	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Hydronephrosis	3 (0.6)	0	0	0	3 (0.4)	0	3 (0.6)	0	0	0	3 (0.4)	0
Hyperkalaemia*	2 (0.4)	0	0	0	2 (0.3)	0	3 (0.6)	0	0	0	3 (0.4)	0
Hypoesthesia*	2 (0.4)	0	2 (1.0)	0	4 (0.5)	0	3 (0.6)	1 (0.2)	3 (1.5)	0	6 (0.8)	1 (0.1)
Hypocalcaemia	2 (0.4)	0	3 (1.5)	1 (0.5)	5 (0.7)	1 (0.1)	3 (0.6)	0	3 (1.5)	1 (0.5)	6 (0.8)	1 (0.1)
*												
Leukopenia	3 (0.6)	2 (0.4)	2 (1.0)	2 (1.0)	5 (0.7)	4 (0.5)	3 (0.6)	2 (0.4)	2 (1.0)	2 (1.0)	5 (0.7)	4 (0.5)
Malaise	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0
Neck pain*	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	3 (0.6)	1 (0.2)	0	0	3 (0.4)	1 (0.1)
Neuropathy peripheral*	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	3 (0.6)	0	1 (0.5)	0	4 (0.5)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Pulmonary embolism	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Sepsis	3 (0.6)	3 (0.6)	2 (1.0)	1 (0.5)	5 (0.7)	4 (0.5)	3 (0.6)	3 (0.6)	2 (1.0)	1 (0.5)	5 (0.7)	4 (0.5)
Urinary retention	3 (0.6)	0	3 (1.5)	0	6 (0.8)	0	3 (0.6)	0	3 (1.5)	0	6 (0.8)	0
Abdominal pain upper	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Adrenal insufficiency	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)
Anxiety*	1 (0.2)	0	3 (1.5)	0	4 (0.5)	0	2 (0.4)	1 (0.2)	3 (1.5)	0	5 (0.7)	1 (0.1)
Balance disorder*	1 (0.2)	0	0	0	1 (0.1)	0	2 (0.4)	0	0	0	2 (0.3)	0
Blood alkaline phosphatase increased	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)
Blood lactate dehydrogenase increased	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
COVID-19	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Colitis	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Dizziness	2 (0.4)	0	6 (2.9)	0	8 (1.1)	0	2 (0.4)	0	6 (2.9)	0	8 (1.1)	0
Dry mouth	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Dry skin	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Dyspnoea exertional	2 (0.4)	0	6 (2.9)	0	8 (1.1)	0	2 (0.4)	0	6 (2.9)	0	8 (1.1)	0
Euthanasia	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Flatulence*	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Groin pain	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)	2 (0.4)	1 (0.2)	1 (0.5)	0	3 (0.4)	1 (0.1)
Hypoalbuminaemia	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Muscular weakness	2 (0.4)	1 (0.2)	2 (1.0)	0	4 (0.5)	1 (0.1)	2 (0.4)	1 (0.2)	2 (1.0)	0	4 (0.5)	1 (0.1)
Musculoskeletal chest pain	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Non-cardiac chest pain*	1 (0.2)	0	0	0	1 (0.1)	0	2 (0.4)	0	0	0	2 (0.3)	0
Paraesthesia	2 (0.4)	0	2 (1.0)	0	4 (0.5)	0	2 (0.4)	0	2 (1.0)	0	4 (0.5)	0
Pelvic pain	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Pneumonia	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)
Productive cough	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0	2 (0.4)	0	1 (0.5)	0	3 (0.4)	0
Renal failure	2 (0.4)	1 (0.2)	3 (1.5)	0	5 (0.7)	1 (0.1)	2 (0.4)	1 (0.2)	3 (1.5)	0	5 (0.7)	1 (0.1)
Skin ulcer	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Somnolence	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Spinal compression fracture	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Spinal cord compression*	1 (0.2)	0	3 (1.5)	1 (0.5)	4 (0.5)	1 (0.1)	2 (0.4)	1 (0.2)	3 (1.5)	1 (0.5)	5 (0.7)	2 (0.3)
Stomatitis*	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0	2 (0.4)	0	2 (1.0)	0	4 (0.5)	0
Abdominal discomfort*	0	0	1 (0.5)	0	1 (0.1)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Abdominal distension	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0
Abnormal loss of weight	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Acidosis*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Acute respiratory failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Affective disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Alanine aminotransferase increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Alopecia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Anaphylactic reaction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Angina pectoris	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Angiopathy*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Aspartate aminotransferase increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Atrial fibrillation	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Bladder pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Blood creatinine increased	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Cardiac arrest	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Cellulitis	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Cerebral ischaemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cerebrovascular accident	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cholecystectomy	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Chronic kidney disease	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Cognitive disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Confusional state	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Contusion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cough	1 (0.2)	0	4 (2.0)	0	5 (0.7)	0	1 (0.2)	0	4 (2.0)	0	5 (0.7)	0
Diverticulum	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dyspepsia	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Dysphagia*	0	0	2 (1.0)	0	2 (0.3)	0	1 (0.2)	0	2 (1.0)	0	3 (0.4)	0
Eccymosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Escherichia sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Face injury*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Facial paralysis*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Gastric ulcer	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Gastroenteritis	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
General physical condition abnormal	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Gingival pain	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Haemorrhage intracranial	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hallucination	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Head discomfort	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hepatic enzyme increased	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hernia pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Herpes zoster	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Hip fracture	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hydrocephalus	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hyperglycaemia	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Hypertension*	0	0	1 (0.5)	0	1 (0.1)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Hypertrophy	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hypoesthesia oral	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Hypokalaemia	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)
Infusion related reaction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Inguinal hernia repair	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
International normalised ratio increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Intestinal obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Irritability	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Joint swelling*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Large intestinal obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Leukocytosis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Lipase increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Lymphoedema	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Malnutrition	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Memory impairment	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Mental status changes	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Mucosal inflammation	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Muscle spasms	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Musculoskeletal discomfort	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Musculoskeletal stiffness	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Myocardial infarction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Nail disorder*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Osteonecrosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pain management	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pallor	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Parosmia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Penile oedema*	0	0	1 (0.5)	0	1 (0.1)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Peripheral sensorimotor neuropathy	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Peripheral swelling*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Pharyngitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pleural effusion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pneumonitis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pollakiuria	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Presyncope	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Respiratory tract infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Scrotal oedema*	0	0	1 (0.5)	0	1 (0.1)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Seasonal allergy	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Skin laceration	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Skin neoplasm excision	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Small intestinal obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Spinal fracture	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Spinal pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Subarachnoid haemorrhage	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Subdural haematoma	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Taste disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Thrombotic thrombocytopenic purpura	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Upper gastrointestinal haemorrhage*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Upper limb fracture	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Ureteric obstruction*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Urinary tract obstruction*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Urinary tract pain*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Urosepsis	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Vision blurred	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Acute hepatic failure	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Anal hypoesthesia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Anal incontinence	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Ascites	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Bronchopneumopathy	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Bursitis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Cardiac failure	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Cell death	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Cerebral haemorrhage	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Chills	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Cholestasis	0	0	2 (1.0)	0	2 (0.3)	0	0	0	2 (1.0)	0	2 (0.3)	0
Colectomy	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Coronary artery disease	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Cushingoid	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Device related infection	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Dysgeusia	0	0	4 (2.0)	0	4 (0.5)	0	0	0	4 (2.0)	0	4 (0.5)	0
Dysuria	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Eczema	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Electrolyte imbalance	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Embolic cerebral infarction	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Erectile dysfunction	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Escherichia urinary tract infection	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Fluid retention	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Gait disturbance	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Gastrointestinal haemorrhage	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Gastrointestinal motility disorder	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Gastrooesophageal reflux disease	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Haemorrhoids	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Hepatic cytolysis	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Hot flush	0	0	2 (1.0)	0	2 (0.3)	0	0	0	2 (1.0)	0	2 (0.3)	0
Hyperhidrosis*	0	0	0	0	0	0	0	0	1 (0.5)	0	1 (0.1)	0
Hypogeausia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Hypotension	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Incontinence	0	0	2 (1.0)	0	2 (0.3)	0	0	0	2 (1.0)	0	2 (0.3)	0
Intramedullary rod insertion	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Ischaemic stroke	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Jugular vein thrombosis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Lactic acidosis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Left ventricular failure	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Lethargy	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Microangiopathic haemolytic anaemia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Mouth ulceration	0	0	2 (1.0)	0	2 (0.3)	0	0	0	2 (1.0)	0	2 (0.3)	0
Myalgia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Myocardial ischaemia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Nasal congestion	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Neuralgia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Nocturia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Oedema	0	0	2 (1.0)	0	2 (0.3)	0	0	0	2 (1.0)	0	2 (0.3)	0
Oral dysaesthesia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Orchitis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Oropharyngeal discomfort	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Oxygen saturation decreased	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pain in jaw	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Paraesthesia oral	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pathological fracture	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Penile haemorrhage	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pericardial effusion	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Peripheral motor neuropathy	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Petechia	0	0	2 (1.0)	0	2 (0.3)	0	0	0	2 (1.0)	0	2 (0.3)	0
Plantar fasciitis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Prostate infection	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pruritus	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Respiratory failure	0	0	3 (1.5)	2 (1.0)	3 (0.4)	2 (0.3)	0	0	3 (1.5)	2 (1.0)	3 (0.4)	2 (0.3)
Sciatica	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Scrotal pain	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Spinal cord disorder	0	0	2 (1.0)	0	2 (0.3)	0	0	0	2 (1.0)	0	2 (0.3)	0
Suspected COVID-19	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Syncope	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Toothache	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Urinary incontinence*	0	0	1 (0.5)	0	1 (0.1)	0	0	0	2 (1.0)	0	2 (0.3)	0
Vertigo	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the Safety Update 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-1-7 2021-09-22 16:37

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aapt.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-2-1 All deaths (FAS safety set)

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Deaths	321 (60.7)	142 (69.3)	463 (63.1)	371 (70.1)	155 (75.6)	526 (71.7)
Primary cause of death						
Disease progression	244 (46.1)	100 (48.8)	344 (46.9)	282 (53.3)	110 (53.7)	392 (53.4)
Unknown	43 (8.1)	21 (10.2)	64 (8.7)	52 (9.8)	23 (11.2)	75 (10.2)
Adverse event	25 (4.7)	13 (6.3)	38 (5.2)	27 (5.1)	13 (6.3)	40 (5.4)
Other	8 (1.5)	6 (2.9)	14 (1.9)	9 (1.7)	7 (3.4)	16 (2.2)
Due to COVID-19	1 (0.2)	2 (1.0)	3 (0.4)	1 (0.2)	2 (1.0)	3 (0.4)
Deaths within 6 weeks of randomization	3 (0.6)	0	3 (0.4)	3 (0.6)	0	3 (0.4)
Primary cause of death within 6 weeks of randomization						
Adverse event	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Disease progression	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Other	0	0	0	0	0	0
Unknown	0	0	0	0	0	0
Due to COVID-19	0	0	0	0	0	0
Deaths within 12 weeks of randomization	9 (1.7)	18 (8.8)	27 (3.7)	9 (1.7)	18 (8.8)	27 (3.7)
Primary cause of death within 12 weeks of randomization						
Adverse event	6 (1.1)	4 (2.0)	10 (1.4)	6 (1.1)	4 (2.0)	10 (1.4)
Disease progression	3 (0.6)	13 (6.3)	16 (2.2)	3 (0.6)	13 (6.3)	16 (2.2)
Other	0	0	0	0	0	0
Unknown	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Due to COVID-19	0	0	0	0	0	0

Output ID: T-2-1-2-1 2021-09-22 16:51

...\\BIOMETRYPROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGMlt-dth.sas

Source data: adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-2-1s All deaths (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Deaths	6 (20.0)
Primary cause of death	
Disease progression	4 (13.3)
Adverse event	2 (6.7)
Other	0
Unknown	0
Due to COVID-19	0
Deaths within 6 weeks of treatment start	0
Primary cause of death within 6 weeks of treatment start	
Adverse event	0
Disease progression	0
Other	0
Unknown	0
Due to COVID-19	0
Deaths within 12 weeks of treatment start	1 (3.3)
Primary cause of death within 12 weeks of treatment start	
Adverse event	1 (3.3)
Disease progression	0
Other	0
Unknown	0
Due to COVID-19	0

Output ID: T-2-1-2-1s 2021-09-22 16:51
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PRODUCTION\\TLF\\PGM\\t-dth.sas
Source data: adsl.xpt
Data Cutoff Date: 28JUN2021

Table 2-1-2-2 On-treatment deaths (FAS safety set)

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Deaths ^a	66 (12.5)	19 (9.3)	85 (11.6)	68 (12.9)	19 (9.3)	87 (11.9)
Primary cause of death						
Disease progression	44 (8.3)	14 (6.8)	58 (7.9)	45 (8.5)	14 (6.8)	59 (8.0)
Adverse event	17 (3.2)	4 (2.0)	21 (2.9)	17 (3.2)	4 (2.0)	21 (2.9)
Unknown	3 (0.6)	0	3 (0.4)	4 (0.8)	0	4 (0.5)
Other	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
Due to COVID-19	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)

^a On-treatment deaths are deaths that occurred during randomized treatment or within 30 days of randomized treatment discontinuation.

Output ID: T-2-1-2-2 2021-09-22 16:51

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-dth.sas

Source data: adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-2-2s On-treatment deaths (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Deaths ^a	5 (16.7)
Primary cause of death	
Disease progression	3 (10.0)
Adverse event	2 (6.7)
Other	0
Unknown	0
Due to COVID-19	0

^a On-treatment deaths are deaths that occurred during study treatment or within 30 days of study treatment discontinuation.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-2-2s 2021-09-22 16:51

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\

PRODUCTION\\TLF\\PGM\\t-dth.sas

Source data: adsf.xpt

Data Cutoff Date: 28JUN2021

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177Lu-PSMA-617 SCS update

Final Version

Table 2-1-2-3 Randomized serious treatment-emergent adverse events leading to fatal outcome (FAS safety set)

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
SAEs with fatal outcome	19 (3.6)	6 (2.9)	25 (3.4)	19 (3.6)	6 (2.9)	25 (3.4)
Reported in patients with primary reason for death = Disease progression	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
General physical health deterioration	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Reported in patients with primary reason for death = Adverse event	19 (3.6)	5 (2.4)	24 (3.3)	19 (3.6)	5 (2.4)	24 (3.3)
Sepsis	4 (0.8)	0	4 (0.5)	4 (0.8)	0	4 (0.5)
Pancytopenia	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Acute hepatic failure	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Bone marrow failure	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
COVID-19	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Disease progression	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
Escherichia sepsis	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Euthanasia	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Hepatic failure	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Ischaemic stroke	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Metastases to central nervous system	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Multiple organ dysfunction syndrome	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Pneumonia aspiration	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Subdural haematoma	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
Arteriosclerosis	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Cardio-respiratory arrest	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Pneumonia	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)

A patient may have more than one SAE with fatal outcome.

Preferred terms are sorted within primary reason for death in descending frequency, as reported in the Safety Update 'Lu-PSMA617+BSC/BSoC' column.

Coded using MedDRA version 24.0

Output ID: T-2-1-2-3 2021-09-22 16:54

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-2-3s Serious study treatment-emergent adverse events leading to fatal outcome (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
SAEs with fatal outcome	2 (6.7)
Reported in patients with primary reason for death = Adverse event	2 (6.7)
End stage renal disease	1 (3.3)
General physical health deterioration	1 (3.3)

A patient may have more than one AE with fatal outcome (Grade 5).

Coded using MedDRA version 24.0

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-2-3s 2021-09-22 16:54

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-2-4 Adverse events during long-term follow-up leading to fatal outcome (FAS safety set)

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
AEs with fatal outcome*	7 (1.3)	7 (3.4)	14 (1.9)	10 (1.9)	7 (3.4)	17 (2.3)
Reported in patients with primary reason for death = Disease progression*	0	0	0	1 (0.2)	0	1 (0.1)
General physical health deterioration*	0	0	0	1 (0.2)	0	1 (0.1)
Reported in patients with primary reason for death = Adverse event*	7 (1.3)	7 (3.4)	14 (1.9)	9 (1.7)	7 (3.4)	16 (2.2)
Euthanasia	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Acute kidney injury	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Acute respiratory failure	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Angiopathy*	0	0	0	1 (0.2)	0	1 (0.1)
Cardiac arrest	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Pneumonia	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Upper gastrointestinal haemorrhage*	0	0	0	1 (0.2)	0	1 (0.1)
Cerebral haemorrhage	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Gastrointestinal haemorrhage	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Respiratory failure	0	2 (1.0)	2 (0.3)	0	2 (1.0)	2 (0.3)
Sepsis	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Suspected COVID-19	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)

A patient may have more than one AE with fatal outcome (Grade 5).

Preferred terms are sorted within primary reason for death in descending frequency, as reported in the Safety Update 'Lu-PSMA617+BSC/BSoC' column.

Coded using MedDRA version 24.0

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-2-4 2021-09-22 16:54

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Number of patients with at least one event			
Grade 1	195 (36.9) [353]	58 (28.3) [90]	253 (34.5) [443]
Grade 2	0 (0.0) [8]	0	0 (0.0) [8]
Grade 3	23 (4.3) [57]	5 (2.4) [16]	28 (3.8) [73]
Grade 4	139 (26.3) [253]	41 (20.0) [61]	180 (24.5) [314]
Grade 5	14 (2.6) [16]	6 (2.9) [7]	20 (2.7) [23]
Grade 3-5	19 (3.6) [19]	6 (2.9) [6]	25 (3.4) [25]
	172 (32.5) [288]	53 (25.9) [74]	225 (30.7) [362]
Blood and lymphatic system disorders			
Grade 1	27 (5.1) [30]	1 (0.5) [1]	28 (3.8) [31]
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]
Grade 4	18 (3.4) [21]	0	18 (2.5) [21]
Grade 5	3 (0.6) [3]	0	3 (0.4) [3]
Grade 3-5	3 (0.6) [3]	0	3 (0.4) [3]
	24 (4.5) [27]	0	24 (3.3) [27]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

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Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Anaemia	15 (2.8) [15]	1 (0.5) [1]	16 (2.2) [16]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 3	14 (2.6) [14]	0	14 (1.9) [14]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	14 (2.6) [14]	0	14 (1.9) [14]
Pancytopenia	6 (1.1) [6]	0	6 (0.8) [6]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	2 (0.4) [2]	0	2 (0.3) [2]
Grade 5	2 (0.4) [2]	0	2 (0.3) [2]
Grade 3-5	6 (1.1) [6]	0	6 (0.8) [6]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Thrombocytopenia	3 (0.6) [3]	0	3 (0.4) [3]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	3 (0.6) [3]	0	3 (0.4) [3]
Febrile neutropenia	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	1 (0.2) [1]	0	1 (0.1) [1]
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

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Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Leukopenia	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]
Bone marrow failure	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Neutropenia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Cardiac disorders	8 (1.5) [9]	2 (1.0) [2]	10 (1.4) [11]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	7 (1.3) [8]	1 (0.5) [1]	8 (1.1) [9]
Grade 4	0	0	0
Grade 5	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3-5	7 (1.3) [8]	2 (1.0) [2]	9 (1.2) [10]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Cardiac failure congestive	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]
Ventricular tachycardia	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Arrhythmia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Atrial fibrillation	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Cardiac failure	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Cardiomyopathy	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Myocardial infarction	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Cardio-respiratory arrest	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

..\BIOMETRY\PROJECTS\PSMA617\VISION\SAFETY_UPDATE_90DAYS\PRODUCTION\TLF\PGM\t-aesocptsev.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Supraventricular tachycardia	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Congenital, familial and genetic disorders	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Vascular malformation	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Ear and labyrinth disorders	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Vertigo	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Endocrine disorders	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	1 (0.5) [1]	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Adrenal insufficiency	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Inappropriate antidiuretic hormone secretion	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	1 (0.5) [1]	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Eye disorders	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Vision blurred	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Gastrointestinal disorders			
Grade 1	27 (5.1) [35]	8 (3.9) [12]	35 (4.8) [47]
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	5 (0.9) [7]	2 (1.0) [3]	7 (1.0) [10]
Grade 4	20 (3.8) [26]	6 (2.9) [9]	26 (3.5) [35]
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	0	0	0
	21 (4.0) [27]	6 (2.9) [9]	27 (3.7) [36]
Constipation			
Grade 1	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	4 (0.8) [4]	1 (0.5) [1]	5 (0.7) [5]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	5 (0.7) [5]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Vomiting	5 (0.9) [7]	1 (0.5) [1]	6 (0.8) [8]
Grade 1	1 (0.2) [1]	0	1 (0.1) [1]
Grade 2	1 (0.2) [2]	0	1 (0.1) [2]
Grade 3	3 (0.6) [4]	1 (0.5) [1]	4 (0.5) [5]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	3 (0.6) [4]	1 (0.5) [1]	4 (0.5) [5]
Abdominal pain	4 (0.8) [4]	1 (0.5) [1]	5 (0.7) [5]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	3 (0.6) [3]	1 (0.5) [1]	4 (0.5) [4]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	3 (0.6) [3]	1 (0.5) [1]	4 (0.5) [4]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Nausea	3 (0.6) [4]	1 (0.5) [1]	4 (0.5) [5]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	2 (0.4) [3]	1 (0.5) [1]	3 (0.4) [4]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [3]	1 (0.5) [1]	3 (0.4) [4]
Abdominal pain lower	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Ascites	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Duodenal ulcer	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Dysphagia	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Gastric haemorrhage	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Gastroesophageal reflux disease	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Haematemesis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Intestinal perforation	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Intestinal pseudo-obstruction	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

..\BIOMETRY\PROJECTS\PSMA617\VISION\SAFETY_UPDATE_90DAYS\PRODUCTION\TLF\PGM\t-aesocptsev.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Large intestinal obstruction	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Lower gastrointestinal haemorrhage	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Rectal haemorrhage	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Small intestinal obstruction	1 (0.2) [1]	1 (0.5) [2]	2 (0.3) [3]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [2]	1 (0.1) [2]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Stomatitis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Upper gastrointestinal haemorrhage	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Diarrhoea	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Gastrointestinal haemorrhage	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Intestinal obstruction	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Volvulus	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
General disorders and administration site conditions			
Grade 1	22 (4.2) [24]	6 (2.9) [6]	28 (3.8) [30]
Grade 2	4 (0.8) [4]	0	4 (0.5) [4]
Grade 3	5 (0.9) [7]	2 (1.0) [2]	7 (1.0) [9]
Grade 4	10 (1.9) [10]	1 (0.5) [1]	11 (1.5) [11]
Grade 5	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3-5	3 (0.6) [3]	2 (1.0) [2]	5 (0.7) [5]
	13 (2.5) [13]	4 (2.0) [4]	17 (2.3) [17]
Pyrexia			
Grade 1	8 (1.5) [8]	0	8 (1.1) [8]
Grade 2	4 (0.8) [4]	0	4 (0.5) [4]
Grade 3	3 (0.6) [3]	0	3 (0.4) [3]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	0	0
	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Pain	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Disease progression	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 3-5	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Fatigue	2 (0.4) [3]	0	2 (0.3) [3]
Grade 1	0	0	0
Grade 2	1 (0.2) [2]	0	1 (0.1) [2]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Euthanasia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Generalised oedema	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Malaise	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Multiple organ dysfunction syndrome	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Oedema peripheral	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Systemic inflammatory response syndrome	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Asthenia	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	1 (0.5) [1]	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
General physical health deterioration	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Influenza like illness	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Oedema	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Hepatobiliary disorders	6 (1.1) [6]	2 (1.0) [2]	8 (1.1) [8]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 3	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	2 (0.4) [2]	0	2 (0.3) [2]
Grade 3-5	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

..\BIOMETRY\PROJECTS\PSMA617\VISION\SAFETY_UPDATE_90DAYS\PRODUCTION\TLF\PGM\t-aesocptsev.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Acute hepatic failure	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Bile duct stenosis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Cholecystitis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Cholestasis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Hepatic failure	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Hepatic lesion	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Hepatic cytolysis	0	2 (1.0) [2]	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Infections and infestations	53 (10.0) [63]	9 (4.4) [10]	62 (8.4) [73]
Grade 1	0	0	0
Grade 2	4 (0.8) [4]	2 (1.0) [2]	6 (0.8) [6]
Grade 3	39 (7.4) [49]	6 (2.9) [7]	45 (6.1) [56]
Grade 4	4 (0.8) [4]	0	4 (0.5) [4]
Grade 5	6 (1.1) [6]	1 (0.5) [1]	7 (1.0) [7]
Grade 3-5	49 (9.3) [59]	7 (3.4) [8]	56 (7.6) [67]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Urinary tract infection	13 (2.5) [15]	1 (0.5) [1]	14 (1.9) [16]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	13 (2.5) [15]	1 (0.5) [1]	14 (1.9) [16]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	13 (2.5) [15]	1 (0.5) [1]	14 (1.9) [16]
Sepsis	10 (1.9) [10]	2 (1.0) [2]	12 (1.6) [12]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	3 (0.6) [3]	2 (1.0) [2]	5 (0.7) [5]
Grade 4	2 (0.4) [2]	0	2 (0.3) [2]
Grade 5	4 (0.8) [4]	0	4 (0.5) [4]
Grade 3-5	9 (1.7) [9]	2 (1.0) [2]	11 (1.5) [11]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Pneumonia			
Grade 1	7 (1.3) [7]	3 (1.5) [4]	10 (1.4) [11]
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	7 (1.3) [7]	1 (0.5) [2]	8 (1.1) [9]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
	7 (1.3) [7]	2 (1.0) [3]	9 (1.2) [10]
Infection			
Grade 1	3 (0.6) [3]	2 (1.0) [2]	5 (0.7) [5]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	3 (0.6) [3]	2 (1.0) [2]	5 (0.7) [5]
Grade 5	0	0	0
Grade 3-5	0	2 (1.0) [2]	5 (0.7) [5]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Urosepsis	3 (0.6) [3]	0	3 (0.4) [3]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	3 (0.6) [3]	0	3 (0.4) [3]
Appendicitis	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Septic shock	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]
Bacterial sepsis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Bronchitis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
COVID-19	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Diverticulitis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Enterococcal bacteraemia	1 (0.2) [2]	0	1 (0.1) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [2]	0	1 (0.1) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [2]	0	1 (0.1) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Enterocolitis infectious	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Escherichia sepsis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

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Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Extradural abscess	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Fungaemia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

..\BIOMETRY\PROJECTS\PSMA617\VISION\SAFETY_UPDATE_90DAYS\PRODUCTION\TLF\PGM\t-aesocptsev.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Herpes zoster	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Kidney infection	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Klebsiella sepsis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Lower respiratory tract infection	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Osteomyelitis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Pyelonephritis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Pyelonephritis acute	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Staphylococcal bacteraemia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Streptococcal bacteraemia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Viral infection	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Wound infection	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Pharyngitis	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Injury, poisoning and procedural complications			
Grade 1	12 (2.3) [13]	6 (2.9) [7]	18 (2.5) [20]
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 4	9 (1.7) [10]	4 (2.0) [5]	13 (1.8) [15]
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	11 (2.1) [12]	1 (0.5) [1]	2 (0.3) [2]
	5 (2.4) [6]	16 (2.2) [18]	
Subdural haematoma			
Grade 1	4 (0.8) [4]	2 (1.0) [2]	6 (0.8) [6]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	3 (0.6) [3]	1 (0.5) [1]	4 (0.5) [4]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
	4 (0.8) [4]	6 (0.8) [6]	

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Spinal fracture	2 (0.4) [3]	0	2 (0.3) [3]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [3]	0	2 (0.3) [3]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [3]	0	2 (0.3) [3]
Acetabulum fracture	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Fall	1 (0.2) [1]	1 (0.5) [2]	2 (0.3) [3]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	1 (0.5) [2]	1 (0.1) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [2]	1 (0.1) [2]
Femoral neck fracture	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Femur fracture	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Hip fracture	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Overdose	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Muscle strain	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Rib fracture	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Wound complication	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Investigations	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Blood creatinine increased	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Metabolism and nutrition disorders			
Grade 1	13 (2.5) [14]	6 (2.9) [6]	19 (2.6) [20]
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	2 (1.0) [2]	3 (0.4) [3]
Grade 4	11 (2.1) [12]	3 (1.5) [3]	14 (1.9) [15]
Grade 5	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 3-5	0	0	0
	12 (2.3) [13]	4 (2.0) [4]	16 (2.2) [17]
Dehydration			
Grade 1	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	6 (0.8) [6]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term				
Maximum grade				
Failure to thrive		2 (0.4) [2]	0	2 (0.3) [2]
Grade 1		0	0	0
Grade 2		0	0	0
Grade 3		2 (0.4) [2]	0	2 (0.3) [2]
Grade 4		0	0	0
Grade 5		0	0	0
Grade 3-5		2 (0.4) [2]	0	2 (0.3) [2]
Hypokalaemia		2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]
Grade 1		0	0	0
Grade 2		0	1 (0.5) [1]	1 (0.1) [1]
Grade 3		2 (0.4) [2]	0	2 (0.3) [2]
Grade 4		0	0	0
Grade 5		0	0	0
Grade 3-5		2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Cachexia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Decreased appetite	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Hypocalcaemia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Hypoglycaemia	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Tumour lysis syndrome	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Hypervolaemia	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Hyponatraemia	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Hypophosphataemia	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	1 (0.5) [1]	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Musculoskeletal and connective tissue disorders	25 (4.7) [29]	5 (2.4) [6]	30 (4.1) [35]
Grade 1	0	0	0
Grade 2	5 (0.9) [6]	0 (0.0) [1]	5 (0.7) [7]
Grade 3	20 (3.8) [23]	5 (2.4) [5]	25 (3.4) [28]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	20 (3.8) [23]	5 (2.4) [5]	25 (3.4) [28]
Back pain	10 (1.9) [10]	3 (1.5) [3]	13 (1.8) [13]
Grade 1	0	0	0
Grade 2	2 (0.4) [2]	0	2 (0.3) [2]
Grade 3	8 (1.5) [8]	3 (1.5) [3]	11 (1.5) [11]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	8 (1.5) [8]	3 (1.5) [3]	11 (1.5) [11]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Bone pain	6 (1.1) [7]	2 (1.0) [3]	8 (1.1) [10]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0 (0.0) [1]	1 (0.1) [2]
Grade 3	5 (0.9) [6]	2 (1.0) [2]	7 (1.0) [8]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	5 (0.9) [6]	2 (1.0) [2]	7 (1.0) [8]
Arthralgia	2 (0.4) [3]	0	2 (0.3) [3]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [3]	0	2 (0.3) [3]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [3]	0	2 (0.3) [3]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Neck pain	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Flank pain	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Intervertebral disc compression	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Intervertebral disc protrusion	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Osteolysis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Pain in extremity	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Pathological fracture	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Spinal pain	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Grade 1	4 (0.8) [4] 0	0	4 (0.5) [4] 0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	4 (0.8) [4]	0	4 (0.5) [4]
Metastases to central nervous system			
Grade 1	2 (0.4) [2] 0	0	2 (0.3) [2] 0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Metastases to meninges	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Pancreatic carcinoma	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Nervous system disorders			
Grade 1	36 (6.8) [40]	17 (8.3) [18]	53 (7.2) [58]
Grade 2	1 (0.2) [2]	0	1 (0.1) [2]
Grade 3	10 (1.9) [12]	0	10 (1.4) [12]
Grade 4	22 (4.2) [23]	13 (6.3) [14]	35 (4.8) [37]
Grade 5	1 (0.2) [1]	4 (2.0) [4]	5 (0.7) [5]
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]
	25 (4.7) [26]	17 (8.3) [18]	42 (5.7) [44]
Spinal cord compression			
Grade 1	6 (1.1) [8]	11 (5.4) [11]	17 (2.3) [19]
Grade 2	0 (0.0) [1]	0	0 (0.0) [1]
Grade 3	0	0	0
Grade 4	5 (0.9) [6]	8 (3.9) [8]	13 (1.8) [14]
Grade 5	1 (0.2) [1]	3 (1.5) [3]	4 (0.5) [4]
Grade 3-5	0	0	0
	6 (1.1) [7]	11 (5.4) [11]	17 (2.3) [18]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Syncope	4 (0.8) [4]	0	4 (0.5) [4]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	4 (0.8) [4]	0	4 (0.5) [4]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	4 (0.8) [4]	0	4 (0.5) [4]
Ischaemic stroke	3 (0.6) [3]	0	3 (0.4) [3]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Dizziness	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Haemorrhage intracranial	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	1 (0.2) [1]	0	1 (0.1) [1]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Headache	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Paraesthesia	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Radiculopathy	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]
Cauda equina syndrome	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Cerebellar infarction	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Cerebral haemorrhage	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Cerebral infarction	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Cognitive disorder	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Dysarthria	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Hypoglossal nerve paralysis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

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Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Loss of consciousness	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Metabolic encephalopathy	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Advanced Accelerator Applications, a Novartis Company

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Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Pachymeningitis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Peripheral motor neuropathy	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Seizure	1 (0.2) [2]	0	1 (0.1) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [2]	0	1 (0.1) [2]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Transient ischaemic attack	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Tremor	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Brain oedema	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	1 (0.5) [1]	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Diplegia	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Encephalopathy	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Myelopathy	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Spinal cord disorder	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Psychiatric disorders	6 (1.1) [7]	2 (1.0) [2]	8 (1.1) [9]
Grade 1	0	0	0
Grade 2	1 (0.2) [2]	1 (0.5) [1]	2 (0.3) [3]
Grade 3	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Mental status changes	3 (0.6) [3]	0	3 (0.4) [3]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Confusional state	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]
Delirium	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Mixed anxiety and depressive disorder	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Renal and urinary disorders	25 (4.7) [39]	9 (4.4) [10]	34 (4.6) [49]
Grade 1	0	0	0
Grade 2	2 (0.4) [4]	2 (1.0) [2]	4 (0.5) [6]
Grade 3	23 (4.3) [35]	7 (3.4) [8]	30 (4.1) [43]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	23 (4.3) [35]	7 (3.4) [8]	30 (4.1) [43]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Haematuria	11 (2.1) [14]	1 (0.5) [1]	12 (1.6) [15]
Grade 1	0	0	0
Grade 2	1 (0.2) [2]	0	1 (0.1) [2]
Grade 3	10 (1.9) [12]	1 (0.5) [1]	11 (1.5) [13]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	10 (1.9) [12]	1 (0.5) [1]	11 (1.5) [13]
Acute kidney injury	9 (1.7) [10]	6 (2.9) [6]	15 (2.0) [16]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 3	8 (1.5) [9]	5 (2.4) [5]	13 (1.8) [14]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	8 (1.5) [9]	5 (2.4) [5]	13 (1.8) [14]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Urinary retention	5 (0.9) [6]	2 (1.0) [2]	7 (1.0) [8]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 3	4 (0.8) [5]	1 (0.5) [1]	5 (0.7) [6]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	4 (0.8) [5]	1 (0.5) [1]	5 (0.7) [6]
Urinary tract obstruction	4 (0.8) [4]	0	4 (0.5) [4]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	4 (0.8) [4]	0	4 (0.5) [4]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	4 (0.8) [4]	0	4 (0.5) [4]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Dysuria	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Hydronephrosis	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Malignant urinary tract obstruction	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Nephrolithiasis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Renal tubular acidosis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Reproductive system and breast disorders	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Benign prostatic hyperplasia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Penile pain	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Respiratory, thoracic and mediastinal disorders			
Grade 1	18 (3.4) [20]	5 (2.4) [5]	23 (3.1) [25]
Grade 2	0	0	0
Grade 3	3 (0.6) [3]	0	3 (0.4) [3]
Grade 4	13 (2.5) [14]	5 (2.4) [5]	18 (2.5) [19]
Grade 5	1 (0.2) [2]	0	1 (0.1) [2]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
	15 (2.8) [17]	5 (2.4) [5]	20 (2.7) [22]
Pulmonary embolism			
Grade 1	6 (1.1) [6]	2 (1.0) [2]	8 (1.1) [8]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	6 (1.1) [6]	2 (1.0) [2]	8 (1.1) [8]
Grade 5	0	0	0
Grade 3-5	0	2 (1.0) [2]	8 (1.1) [8]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Dyspnoea	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Grade 1	0	0	0
Grade 2	3 (0.6) [3]	0	3 (0.4) [3]
Grade 3	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]
Pleural effusion	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Acute respiratory failure	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Chronic obstructive pulmonary disease	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Epistaxis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Haemoptysis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Hypoxia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Pneumonia aspiration	1 (0.2) [2]	0	1 (0.1) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0 (0.0) [1]	0	0 (0.0) [1]
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [2]	0	1 (0.1) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Pulmonary hypertension	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Surgical and medical procedures	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Neck dissection	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Pain management	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Vascular disorders			
Grade 1	11 (2.1) [12]	1 (0.5) [1]	12 (1.6) [13]
Grade 2	0	0	0
Grade 3	2 (0.4) [3]	0	2 (0.3) [3]
Grade 4	8 (1.5) [8]	0	8 (1.1) [8]
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
	9 (1.7) [9]	1 (0.5) [1]	10 (1.4) [10]
Hypotension			
Grade 1	4 (0.8) [4]	0	4 (0.5) [4]
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	3 (0.6) [3]	0	3 (0.4) [3]
Grade 5	0	0	0
Grade 3-5	0	0	0
	3 (0.6) [3]	0	3 (0.4) [3]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Deep vein thrombosis	3 (0.6) [4] 0	0	3 (0.4) [4] 0
Grade 1	0	0	0
Grade 2	1 (0.2) [2]	0	1 (0.1) [2]
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]
Embolism	2 (0.4) [2] 0	0	2 (0.3) [2] 0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Aortic stenosis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Orthostatic hypotension	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1 Randomized serious treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Arteriosclerosis	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Output ID: T-2-1-3-1 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Number of patients with at least one event	8 (26.7) [18]
Grade 1	1 (3.3) [2]
Grade 2	0 (0.0) [2]
Grade 3	3 (10.0) [10]
Grade 4	2 (6.7) [2]
Grade 5	2 (6.7) [2]
Grade 3-5	7 (23.3) [14]
Blood and lymphatic system disorders	3 (10.0) [4]
Grade 1	0
Grade 2	0
Grade 3	2 (6.7) [3]
Grade 4	1 (3.3) [1]
Grade 5	0
Grade 3-5	3 (10.0) [4]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Anaemia	2 (6.7) [2]
Grade 1	0
Grade 2	0
Grade 3	2 (6.7) [2]
Grade 4	0
Grade 5	0
Grade 3-5	2 (6.7) [2]
Thrombocytopenia	2 (6.7) [2]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	1 (3.3) [1]
Grade 5	0
Grade 3-5	2 (6.7) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGMT-aesocptsev.sas

Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
General disorders and administration site conditions	2 (6.7) [2]
Grade 1	0
Grade 2	1 (3.3) [1]
Grade 3	0
Grade 4	0
Grade 5	1 (3.3) [1]
Grade 3-5	1 (3.3) [1]
General physical health deterioration	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	0
Grade 4	0
Grade 5	1 (3.3) [1]
Grade 3-5	1 (3.3) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Pyrexia	1 (3.3) [1]
Grade 1	0
Grade 2	1 (3.3) [1]
Grade 3	0
Grade 4	0
Grade 5	0
Grade 3-5	0
Metabolism and nutrition disorders	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Dehydration	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]
Musculoskeletal and connective tissue disorders	3 (10.0) [4]
Grade 1	1 (3.3) [1]
Grade 2	0 (0.0) [1]
Grade 3	2 (6.7) [2]
Grade 4	0
Grade 5	0
Grade 3-5	2 (6.7) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Back pain	1 (3.3) [1]
Grade 1	1 (3.3) [1]
Grade 2	0
Grade 3	0
Grade 4	0
Grade 5	0
Grade 3-5	0
Bone pain	1 (3.3) [2]
Grade 1	0
Grade 2	0 (0.0) [1]
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Spinal stenosis	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Cancer pain	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]
Nervous system disorders	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	0
Grade 4	1 (3.3) [1]
Grade 5	0
Grade 3-5	1 (3.3) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Paraplegia	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	0
Grade 4	1 (3.3) [1]
Grade 5	0
Grade 3-5	1 (3.3) [1]
Renal and urinary disorders	2 (6.7) [2]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	1 (3.3) [1]
Grade 3-5	2 (6.7) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
End stage renal disease	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	0
Grade 4	0
Grade 5	1 (3.3) [1]
Grade 3-5	1 (3.3) [1]
Urinary retention	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Data Cutoff Date: 28JUN2021

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Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class	Preferred term	Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Respiratory, thoracic and mediastinal disorders			3 (10.0) [3]
Grade 1			1 (3.3) [1]
Grade 2			0
Grade 3			2 (6.7) [2]
Grade 4			0
Grade 5			0
Grade 3-5			2 (6.7) [2]
Dyspnoea			1 (3.3) [1]
Grade 1			1 (3.3) [1]
Grade 2			0
Grade 3			0
Grade 4			0
Grade 5			0
Grade 3-5			0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-1s Serious study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Pleural effusion	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]
Pulmonary embolism	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-1s 2021-09-22 16:40

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-2 Randomized serious treatment-emergent adverse events by preferred term (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event*	192 (36.3)	169 (31.9)	57 (27.8)	52 (25.4)	249 (33.9)	221 (30.1)	195 (36.9)	172 (32.5)	58 (28.3)	53 (25.9)	253 (34.5)	225 (30.7)
Anaemia	15 (2.8)	14 (2.6)	1 (0.5)	0	16 (2.2)	14 (1.9)	15 (2.8)	14 (2.6)	1 (0.5)	0	16 (2.2)	14 (1.9)
Urinary tract infection	13 (2.5)	13 (2.5)	1 (0.5)	1 (0.5)	14 (1.9)	14 (1.9)	13 (2.5)	13 (2.5)	1 (0.5)	1 (0.5)	14 (1.9)	14 (1.9)
Haematuria	11 (2.1)	10 (1.9)	1 (0.5)	1 (0.5)	12 (1.6)	11 (1.5)	11 (2.1)	10 (1.9)	1 (0.5)	1 (0.5)	12 (1.6)	11 (1.5)
Back pain*	9 (1.7)	7 (1.3)	3 (1.5)	3 (1.5)	12 (1.6)	10 (1.4)	10 (1.9)	8 (1.5)	3 (1.5)	3 (1.5)	13 (1.8)	11 (1.5)
Sepsis	10 (1.9)	9 (1.7)	2 (1.0)	2 (1.0)	12 (1.6)	11 (1.5)	10 (1.9)	9 (1.7)	2 (1.0)	2 (1.0)	12 (1.6)	11 (1.5)
Acute kidney injury	9 (1.7)	8 (1.5)	6 (2.9)	5 (2.4)	15 (2.0)	13 (1.8)	9 (1.7)	8 (1.5)	6 (2.9)	5 (2.4)	15 (2.0)	13 (1.8)
Pyrexia*	7 (1.3)	1 (0.2)	0	0	7 (1.0)	1 (0.1)	8 (1.5)	1 (0.2)	0	0	8 (1.1)	1 (0.1)
Pneumonia	7 (1.3)	7 (1.3)	3 (1.5)	2 (1.0)	10 (1.4)	9 (1.2)	7 (1.3)	7 (1.3)	3 (1.5)	2 (1.0)	10 (1.4)	9 (1.2)
Bone pain	6 (1.1)	5 (0.9)	2 (1.0)	2 (1.0)	8 (1.1)	7 (1.0)	6 (1.1)	5 (0.9)	2 (1.0)	2 (1.0)	8 (1.1)	7 (1.0)
Pancytopenia	6 (1.1)	6 (1.1)	0	0	6 (0.8)	6 (0.8)	6 (1.1)	6 (1.1)	0	0	6 (0.8)	6 (0.8)
Pulmonary embolism	6 (1.1)	6 (1.1)	2 (1.0)	2 (1.0)	8 (1.1)	8 (1.1)	6 (1.1)	6 (1.1)	2 (1.0)	2 (1.0)	8 (1.1)	8 (1.1)
Spinal cord compression*	6 (1.1)	6 (1.1)	10 (4.9)	10 (4.9)	16 (2.2)	16 (2.2)	6 (1.1)	6 (1.1)	11 (5.4)	11 (5.4)	17 (2.3)	17 (2.3)
Constipation	5 (0.9)	4 (0.8)	1 (0.5)	1 (0.5)	6 (0.8)	5 (0.7)	5 (0.9)	4 (0.8)	1 (0.5)	1 (0.5)	6 (0.8)	5 (0.7)
Dehydration	5 (0.9)	5 (0.9)	1 (0.5)	1 (0.5)	6 (0.8)	6 (0.8)	5 (0.9)	5 (0.9)	1 (0.5)	1 (0.5)	6 (0.8)	6 (0.8)
Dyspnoea	5 (0.9)	2 (0.4)	1 (0.5)	1 (0.5)	6 (0.8)	3 (0.4)	5 (0.9)	2 (0.4)	1 (0.5)	1 (0.5)	6 (0.8)	3 (0.4)
Pain	5 (0.9)	5 (0.9)	1 (0.5)	1 (0.5)	6 (0.8)	6 (0.8)	5 (0.9)	5 (0.9)	1 (0.5)	1 (0.5)	6 (0.8)	6 (0.8)
Urinary retention	5 (0.9)	4 (0.8)	2 (1.0)	1 (0.5)	7 (1.0)	5 (0.7)	5 (0.9)	4 (0.8)	2 (1.0)	1 (0.5)	7 (1.0)	5 (0.7)
Vomiting	5 (0.9)	3 (0.6)	1 (0.5)	1 (0.5)	6 (0.8)	4 (0.5)	5 (0.9)	3 (0.6)	1 (0.5)	1 (0.5)	6 (0.8)	4 (0.5)
Abdominal pain	4 (0.8)	3 (0.6)	1 (0.5)	1 (0.5)	5 (0.7)	4 (0.5)	4 (0.8)	3 (0.6)	1 (0.5)	1 (0.5)	5 (0.7)	4 (0.5)
Hypotension	4 (0.8)	3 (0.6)	0	0	4 (0.5)	3 (0.4)	4 (0.8)	3 (0.6)	0	0	4 (0.5)	3 (0.4)
Subdural haematoma	4 (0.8)	4 (0.8)	2 (1.0)	2 (1.0)	6 (0.8)	6 (0.8)	4 (0.8)	4 (0.8)	2 (1.0)	2 (1.0)	6 (0.8)	6 (0.8)
Syncope	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Urinary tract obstruction	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)
Deep vein thrombosis	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Infection	3 (0.6)	3 (0.6)	2 (1.0)	2 (1.0)	5 (0.7)	5 (0.7)	3 (0.6)	3 (0.6)	2 (1.0)	2 (1.0)	5 (0.7)	5 (0.7)
Ischaemic stroke	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Mental status changes	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Nausea	3 (0.6)	2 (0.4)	1 (0.5)	1 (0.5)	4 (0.5)	3 (0.4)	3 (0.6)	2 (0.4)	1 (0.5)	1 (0.5)	4 (0.5)	3 (0.4)
Thrombocytopenia	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)
Urosepsis	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)	3 (0.6)	3 (0.6)	0	0	3 (0.4)	3 (0.4)
Appendicitis	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Arthralgia	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Cardiac failure	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
congestive												
Confusional state	2 (0.4)	2 (0.4)	1 (0.5)	0	3 (0.4)	2 (0.3)	2 (0.4)	2 (0.4)	1 (0.5)	0	3 (0.4)	2 (0.3)
Disease progression	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)
Dizziness	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Embolism	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Failure to thrive	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Fatigue	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Febrile neutropenia	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Haemorrhage intracranial	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Headache	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Hypokalaemia	2 (0.4)	2 (0.4)	1 (0.5)	0	3 (0.4)	2 (0.3)	2 (0.4)	2 (0.4)	1 (0.5)	0	3 (0.4)	2 (0.3)
Leukopenia	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Metastases to central nervous system	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Neck pain	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Paraesthesia	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Pleural effusion	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)
Radiculopathy	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Septic shock	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Spinal fracture	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Ventricular tachycardia	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Abdominal pain lower*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Acetabulum fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Acute hepatic failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Acute respiratory failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Adrenal insufficiency	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Aortic stenosis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Arrhythmia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Ascites	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Atrial fibrillation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bacterial sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Benign prostatic hyperplasia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bile duct stenosis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bone marrow failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bronchitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Page 3 of 10

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
COVID-19	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cachexia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cardiac failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cardiomyopathy	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cauda equina syndrome	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Cerebellar infarction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cerebral haemorrhage	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cerebral infarction	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cholecystitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cholestasis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Chronic obstructive pulmonary disease	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cognitive disorder	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Decreased appetite	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Delirium	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)
Diverticulitis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Duodenal ulcer	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Dysarthria	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Dysphagia	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Dysuria	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Enterococcal bacteraemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Enterocolitis infectious	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Epistaxis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Escherichia sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Euthanasia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Extradural abscess	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Fall	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)
Femoral neck fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Femur fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Flank pain	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Fungaemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Gastric haemorrhage	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Gastrooesophageal reflux disease	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Generalised oedema	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Haematemesis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Haemoptysis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hepatic failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hepatic lesion	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Herpes zoster	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hip fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hydronephrosis	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Hypocalcaemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hypoglossal nerve paralysis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hypoglycaemia	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Hypoxia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Intervertebral disc compression	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
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	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Intervertebral disc protrusion	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Intestinal perforation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Intestinal pseudo-obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Kidney infection	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Klebsiella sepsis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Large intestinal obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Loss of consciousness	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Lower gastrointestinal haemorrhage	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Lower respiratory tract infection	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Malaise	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Malignant urinary tract obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Metabolic encephalopathy	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Metastases to meninges	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Mixed anxiety and depressive disorder	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Multiple organ dysfunction syndrome	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Myocardial infarction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Neck dissection	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Nephrolithiasis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Neutropenia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Oedema peripheral	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Orthostatic hypotension	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Osteolysis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Osteomyelitis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Overdose	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pachymeningitis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pain in extremity	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pain management	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pancreatic carcinoma*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pathological fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Penile pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Peripheral motor neuropathy	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pneumonia aspiration	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pyelonephritis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pyelonephritis acute	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Rectal haemorrhage	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Renal tubular acidosis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Seizure	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Small intestinal obstruction	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Spinal pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Staphylococcal bacteraemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Stomatitis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Streptococcal bacteraemia*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Systemic inflammatory response syndrome	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Transient ischaemic attack	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Tremor	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Tumour lysis syndrome	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Upper gastrointestinal haemorrhage	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Vascular malformation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Vertigo	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Viral infection	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Vision blurred	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Wound infection	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Arteriosclerosis	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Asthenia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Blood creatinine increased	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Brain oedema	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Cardio-respiratory arrest	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Diarrhoea	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Diplegia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Encephalopathy	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Gastrointestinal haemorrhage	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
General physical health deterioration	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Hepatic cytolysis	0	0	2 (1.0)	1 (0.5)	2 (0.3)	1 (0.1)	0	0	2 (1.0)	1 (0.5)	2 (0.3)	1 (0.1)
Hypervolaemia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Hyponatraemia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Hypophosphataemia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Inappropriate antidiuretic hormone secretion	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Influenza like illness	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Intestinal obstruction*	0	0	0	0	0	0	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Muscle strain	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Myelopathy	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Oedema	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pharyngitis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pulmonary hypertension	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Rib fracture	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Spinal cord disorder	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Supraventricular tachycardia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Volvulus	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Wound complication	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the Safety Update 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-3-2 2021-09-22 16:37

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-2s Serious study treatment-emergent adverse events by preferred term (Sub-study safety analysis set)

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	8 (26.7)	7 (23.3)
Anaemia	2 (6.7)	2 (6.7)
Thrombocytopenia	2 (6.7)	2 (6.7)
Back pain	1 (3.3)	0
Bone pain	1 (3.3)	1 (3.3)
Cancer pain	1 (3.3)	1 (3.3)
Dehydration	1 (3.3)	1 (3.3)
Dyspnoea	1 (3.3)	0
End stage renal disease	1 (3.3)	1 (3.3)
General physical health deterioration	1 (3.3)	1 (3.3)
Paraplegia	1 (3.3)	1 (3.3)
Pleural effusion	1 (3.3)	1 (3.3)
Pulmonary embolism	1 (3.3)	1 (3.3)
Pyrexia	1 (3.3)	0
Spinal stenosis	1 (3.3)	1 (3.3)
Urinary retention	1 (3.3)	1 (3.3)

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-2s 2021-09-22 16:37

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Number of patients with at least one event	51 (9.6) [68]	5 (2.4) [6]	56 (7.6) [74]
Grade 1	1 (0.2) [3]	0	1 (0.1) [3]
Grade 2	4 (0.8) [7]	0 (0.0) [1]	4 (0.5) [8]
Grade 3	35 (6.6) [47]	3 (1.5) [3]	38 (5.2) [50]
Grade 4	6 (1.1) [6]	2 (1.0) [2]	8 (1.1) [8]
Grade 5	5 (0.9) [5]	0	5 (0.7) [5]
Grade 3-5	46 (8.7) [58]	5 (2.4) [5]	51 (6.9) [63]
Blood and lymphatic system disorders	21 (4.0) [24]	0	21 (2.9) [24]
Grade 1	1 (0.2) [1]	0	1 (0.1) [1]
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	13 (2.5) [16]	0	13 (1.8) [16]
Grade 4	3 (0.6) [3]	0	3 (0.4) [3]
Grade 5	3 (0.6) [3]	0	3 (0.4) [3]
Grade 3-5	19 (3.6) [22]	0	19 (2.6) [22]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Anaemia	11 (2.1) [11]	0	11 (1.5) [11]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	10 (1.9) [10]	0	10 (1.4) [10]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	10 (1.9) [10]	0	10 (1.4) [10]
Pancytopenia	5 (0.9) [5]	0	5 (0.7) [5]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	2 (0.4) [2]	0	2 (0.3) [2]
Grade 5	2 (0.4) [2]	0	2 (0.3) [2]
Grade 3-5	5 (0.9) [5]	0	5 (0.7) [5]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Thrombocytopenia	3 (0.6) [3]	0	3 (0.4) [3]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	3 (0.6) [3]	0	3 (0.4) [3]
Leukopenia	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Bone marrow failure	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Febrile neutropenia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	1 (0.2) [1]	0	1 (0.1) [1]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Neutropenia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Cardiac disorders	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Cardiac failure	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Ventricular tachycardia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Endocrine disorders	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	1 (0.5) [1]	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Inappropriate antidiuretic hormone secretion	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	1 (0.5) [1]	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Gastrointestinal disorders	7 (1.3) [9]	1 (0.5) [1]	8 (1.1) [10]
Grade 1	0	0	0
Grade 2	1 (0.2) [2]	0	1 (0.1) [2]
Grade 3	5 (0.9) [6]	1 (0.5) [1]	6 (0.8) [7]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	6 (1.1) [7]	1 (0.5) [1]	7 (1.0) [8]
Constipation	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Nausea	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Vomiting	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Abdominal pain	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Gastric haemorrhage	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Upper gastrointestinal haemorrhage	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Lower gastrointestinal haemorrhage	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
General disorders and administration site conditions			
Grade 1	5 (0.9) [6]	0	5 (0.7) [6]
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0 (0.0) [1]	0	0 (0.0) [1]
Grade 4	4 (0.8) [4]	0	4 (0.5) [4]
Grade 5	0	0	0
Grade 3-5	0	0	0
	4 (0.8) [4]	0	4 (0.5) [4]
Fatigue			
Grade 1	1 (0.2) [2]	0	1 (0.1) [2]
Grade 2	0	0	0
Grade 3	0 (0.0) [1]	0	0 (0.0) [1]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	0	0
	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Generalised oedema	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Oedema peripheral	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Pain	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Pyrexia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	1 (0.2) [1]	0	1 (0.1) [1]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Hepatobiliary disorders	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Hepatic cytosis	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	1 (0.5) [1]	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Infections and infestations	7 (1.3) [8]	0	7 (1.0) [8]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	6 (1.1) [7]	0	6 (0.8) [7]
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	7 (1.3) [8]	0	7 (1.0) [8]
Pneumonia	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Herpes zoster	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Infection	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Sepsis	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Septic shock	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Urinary tract infection	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Wound infection	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Injury, poisoning and procedural complications	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]
Hip fracture	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Subdural haematoma			
Grade 1	1 (0.2) [1]	0	1 (0.1) [1]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Metabolism and nutrition disorders			
Grade 1	4 (0.8) [4]	2 (1.0) [2]	6 (0.8) [6]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	3 (0.6) [3]	1 (0.5) [1]	4 (0.5) [4]
Grade 5	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 3-5	0	0	0
	4 (0.8) [4]	2 (1.0) [2]	6 (0.8) [6]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Dehydration	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Hypocalcaemia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Hypokalaemia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Tumour lysis syndrome	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Hypervolaemia	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]
Hypophosphataemia	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	1 (0.5) [1]	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Musculoskeletal and connective tissue disorders	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Arthralgia	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Nervous system disorders			
Grade 1	5 (0.9) [5]	1 (0.5) [1]	6 (0.8) [6]
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	1 (0.2) [1]	1 (0.5) [1]	2 (0.3) [2]
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
	2 (0.4) [2]	1 (0.5) [1]	3 (0.4) [3]
Haemorrhage intracranial			
Grade 1	2 (0.4) [2]	0	2 (0.3) [2]
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Cerebral infarction	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Seizure	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Syncope	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Spinal cord compression	0	1 (0.5) [1]	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.5) [1]	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	1 (0.5) [1]	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Preferred term			
Maximum grade			
Psychiatric disorders	2 (0.4) [2] 0 1 (0.2) [1] 1 (0.2) [1] 0 0 1 (0.2) [1]	0 0 0 0 0 0	2 (0.3) [2] 0 1 (0.1) [1] 1 (0.1) [1] 0 0 1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]
Confusional state	1 (0.2) [1] 0 0 1 (0.2) [1] 0 0 1 (0.2) [1]	0 0 0 0 0 0	1 (0.1) [1] 0 0 1 (0.1) [1] 0 0 1 (0.1) [1]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (0.2) [1]	0	1 (0.1) [1]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	1 (0.2) [1]	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Delirium	1 (0.2) [1]	0	1 (0.1) [1]
Grade 1	0	0	0
Grade 2	1 (0.2) [1]	0	1 (0.1) [1]
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	0	0	0
Renal and urinary disorders	4 (0.8) [4]	0	4 (0.5) [4]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	4 (0.8) [4]	0	4 (0.5) [4]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	4 (0.8) [4]	0	4 (0.5) [4]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Acute kidney injury	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]
Haematuria	2 (0.4) [2]	0	2 (0.3) [2]
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (0.4) [2]	0	2 (0.3) [2]
Grade 4	0	0	0
Grade 5	0	0	0
Grade 3-5	2 (0.4) [2]	0	2 (0.3) [2]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3 Randomized serious drug-related treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (FAS safety set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Respiratory, thoracic and mediastinal disorders			
Grade 1	1 (0.2) [1]	0	1 (0.1) [1]
Grade 2	0	0	0
Grade 3	0	0	1 (0.1) [1]
Grade 4	1 (0.2) [1]	0	0
Grade 5	0	0	0
Grade 3-5	0	0	1 (0.1) [1]
Pulmonary embolism			
Grade 1	1 (0.2) [1]	0	1 (0.1) [1]
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (0.2) [1]	0	1 (0.1) [1]
Grade 5	0	0	0
Grade 3-5	0	0	1 (0.1) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row.

Total number of events are based on separate records captured in the database.

System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Output ID: T-2-1-3-3 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-3-3s Serious drug-related study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Number of patients with at least one event	2 (6.7) [3]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [2]
Grade 4	1 (3.3) [1]
Grade 5	0
Grade 3-5	2 (6.7) [3]
Blood and lymphatic system disorders	2 (6.7) [3]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [2]
Grade 4	1 (3.3) [1]
Grade 5	0
Grade 3-5	2 (6.7) [3]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-3s 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-3-3s Serious drug-related study treatment-emergent adverse events by system organ class, preferred term and maximum CTC grade (Sub-study safety analysis set)

System organ class Preferred term Maximum grade	Lu-PSMA-617 +BSC/BSoC (N=30)
Thrombocytopenia	2 (6.7) [2]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	1 (3.3) [1]
Grade 5	0
Grade 3-5	2 (6.7) [2]
Anaemia	1 (3.3) [1]
Grade 1	0
Grade 2	0
Grade 3	1 (3.3) [1]
Grade 4	0
Grade 5	0
Grade 3-5	1 (3.3) [1]

Results given as xx (xx.x) [xx] where xx=number of patients, (xx.x)=percentage, [xx]=total number of events for the patients experiencing at least one event per that row. Total number of events are based on separate records captured in the database. System organ classes are presented alphabetically; preferred terms are sorted within system organ class in descending frequency, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Every patient is counted a single time for each applicable specific adverse event with maximum grade. A patient with multiple adverse events within a system organ class is counted a single time for that system organ class with maximum grade.

Coded using MedDRA version 24.0 and NCI CTCAE version 5.0.

Drug-related is related to any study drug (177Lu-PSMA-617 or BSC/BSoC).

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-3-3s 2021-09-22 16:41

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

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177Lu-PSMA-617 SCS update

Table 2-1-4-1s Study treatment-emergent adverse events leading to permanent discontinuation of 177Lu-PSMA-617 by preferred term (Sub-study safety analysis set)

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	2 (6.7)	2 (6.7)
Anaemia	1 (3.3)	1 (3.3)
Thrombocytopenia	1 (3.3)	1 (3.3)

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-4-1s 2021-09-22 16:37

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-4-2 Randomized treatment-emergent adverse events leading to permanent discontinuation of BSC/BSoC by preferred term (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event*	45 (8.5)	25 (4.7)	16 (7.8)	12 (5.9)	61 (8.3)	37 (5.0)	47 (8.9)	26 (4.9)	16 (7.8)	12 (5.9)	63 (8.6)	38 (5.2)
Anaemia	5 (0.9)	4 (0.8)	0	0	5 (0.7)	4 (0.5)	5 (0.9)	4 (0.8)	0	0	5 (0.7)	4 (0.5)
Fatigue	5 (0.9)	0	0	0	5 (0.7)	0	5 (0.9)	0	0	0	5 (0.7)	0
Thrombocytopenia	5 (0.9)	2 (0.4)	0	0	5 (0.7)	2 (0.3)	5 (0.9)	2 (0.4)	0	0	5 (0.7)	2 (0.3)
Adrenal insufficiency	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Decreased appetite	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Dyspnoea*	1 (0.2)	1 (0.2)	2 (1.0)	1 (0.5)	3 (0.4)	2 (0.3)	2 (0.4)	2 (0.4)	2 (1.0)	1 (0.5)	4 (0.5)	3 (0.4)
Leukopenia	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Pancytopenia	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Alanine aminotransferase increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Arthralgia*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Ascites	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Aspartate aminotransferase increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Asthenia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Back pain	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Blood alkaline phosphatase increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cerebral haemorrhage	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cholestasis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Deafness	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Delirium	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Diarrhoea	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dry mouth	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dyspepsia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Failure to thrive	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Gastric haemorrhage	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Haemoptysis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	0	0	0	0	1 (0.1)	1 (0.1)
Headache	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hepatic cytolysis	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Hypocalcaemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hypoglossal nerve paralysis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Ischaemic stroke	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Myocardial infarction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Neck pain	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Oedema peripheral	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Oropharyngeal pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Osteonecrosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Osteonecrosis of jaw*	0	0	0	0	0	0	1 (0.2)	0	0	0	1 (0.1)	0
Pain	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)	1 (0.2)	1 (0.2)	1 (0.5)	1 (0.5)	2 (0.3)	2 (0.3)
Rectal haemorrhage*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	1 (0.1)	1 (0.1)	1 (0.1)
Skin ulcer	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Subdural haematoma	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Tremor*	0	0	0	0	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Tumour lysis syndrome	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Ventricular tachycardia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Vertigo	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Vision blurred	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Wound infection	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Blood creatinine increased	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Bone pain	0	0	2 (1.0)	1 (0.5)	2 (0.3)	1 (0.1)	0	0	2 (1.0)	1 (0.5)	2 (0.3)	1 (0.1)
Cauda equina syndrome	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
General physical health deterioration	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Hypophosphataemia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Nausea	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pneumonia	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Spinal cord compression	0	0	3 (1.5)	3 (1.5)	3 (0.4)	3 (0.4)	0	0	3 (1.5)	3 (1.5)	3 (0.4)	3 (0.4)
Spinal cord disorder	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Urinary retention	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the Safety Update 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-4-2 2021-09-22 16:38

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 2-1-4-2s Study treatment-emergent adverse events leading to permanent discontinuation of BSC/BSoC by preferred term (Sub-study safety analysis set)

No data to report

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-4-2s 2021-09-22 16:38

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-4-3s Study treatment-emergent adverse events leading to interruption of 177Lu-PSMA-617 by preferred term (Sub-study safety analysis set)

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	4 (13.3)	4 (13.3)
Anaemia	1 (3.3)	1 (3.3)
Generalised oedema	1 (3.3)	1 (3.3)
Pain	1 (3.3)	1 (3.3)
Paraplegia	1 (3.3)	1 (3.3)
Pleural effusion	1 (3.3)	1 (3.3)
Pyrexia	1 (3.3)	0
Spinal stenosis	1 (3.3)	1 (3.3)
Thrombocytopenia	1 (3.3)	1 (3.3)
Urinary retention	1 (3.3)	1 (3.3)

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-4-3s 2021-09-22 16:38

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-4-4s Study treatment-emergent adverse events leading to reduction of 177Lu-PSMA-617 by preferred term (Sub-study safety analysis set)

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	2 (6.7)	2 (6.7)
Leukopenia	2 (6.7)	2 (6.7)

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-4-4s 2021-09-22 16:38

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 2-1-4-5 Randomized treatment-emergent adverse events leading to interruption of BSC/BSoC by preferred term (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	50 (9.5)	32 (6.0)	14 (6.8)	9 (4.4)	64 (8.7)	41 (5.6)	50 (9.5)	32 (6.0)	14 (6.8)	9 (4.4)	64 (8.7)	41 (5.6)
Anaemia	9 (1.7)	3 (0.6)	0	0	9 (1.2)	3 (0.4)	9 (1.7)	3 (0.6)	0	0	9 (1.2)	3 (0.4)
Sepsis	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)	4 (0.8)	4 (0.8)	0	0	4 (0.5)	4 (0.5)
Nausea	3 (0.6)	1 (0.2)	1 (0.5)	0	4 (0.5)	1 (0.1)	3 (0.6)	1 (0.2)	1 (0.5)	0	4 (0.5)	1 (0.1)
Thrombocytopoenia	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)	3 (0.6)	2 (0.4)	0	0	3 (0.4)	2 (0.3)
Aspartate aminotransferase increased	2 (0.4)	1 (0.2)	1 (0.5)	1 (0.5)	3 (0.4)	2 (0.3)	2 (0.4)	1 (0.2)	1 (0.5)	1 (0.5)	3 (0.4)	2 (0.3)
Dehydration	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)	2 (0.4)	2 (0.4)	1 (0.5)	1 (0.5)	3 (0.4)	3 (0.4)
Diarrhoea	2 (0.4)	0	0	0	2 (0.3)	0	2 (0.4)	0	0	0	2 (0.3)	0
Dyspnoea	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Fatigue	2 (0.4)	0	1 (0.5)	1 (0.5)	3 (0.4)	1 (0.1)	2 (0.4)	0	1 (0.5)	1 (0.5)	3 (0.4)	1 (0.1)
Haematuria	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Hyperbilirubinaemia	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Hypokalaemia	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Lymphopenia	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Muscular weakness	2 (0.4)	1 (0.2)	1 (0.5)	1 (0.5)	3 (0.4)	2 (0.3)	2 (0.4)	1 (0.2)	1 (0.5)	1 (0.5)	3 (0.4)	2 (0.3)
Pneumonia	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)	2 (0.4)	1 (0.2)	0	0	2 (0.3)	1 (0.1)
Urinary tract infection	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	0	2 (0.3)	2 (0.3)
Abdominal pain	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Acidosis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Acute kidney injury	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Alanine aminotransferase increased	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)
Arthralgia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Bile duct stenosis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Bone pain	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cardiac failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cardiac failure congestive	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cardiomyopathy	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Confusional state	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Constipation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Cystitis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Dental restoration failure	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dizziness	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Enterococcal bacteraemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Epistaxis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Extradural abscess	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Fungaemia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hepatic failure	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hypertension	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Hypocalcaemia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Hypotension	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Ileus	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Intestinal obstruction*	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	1 (0.5)	1 (0.5)	2 (0.3)	1 (0.1)
Leukopenia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Mixed anxiety and depressive disorder	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Muscle spasms	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Osteomyelitis	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pancytopenia	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pleural effusion	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Pulmonary embolism	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Pyrexia	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Rectal haemorrhage	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Seizure	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Spinal fracture	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Urinary retention	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Urinary tract obstruction	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Vascular malformation	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Vomiting	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Blood creatinine increased	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Gastrointestinal haemorrhage	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Hepatic cytolysis	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Hyperkalaemia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Inappropriate antidiuretic hormone secretion	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Lower gastrointestinal haemorrhage	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)
Oedema peripheral	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Pharyngitis	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Transaminases increased	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Volvulus	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)	0	0	1 (0.5)	1 (0.5)	1 (0.1)	1 (0.1)

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the Safety Update 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-4-5 2021-09-22 16:38

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Source data: adsl.xpt, adae.xpt

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Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-4-5s Study treatment-emergent adverse events leading to interruption of BSC/BSoC by preferred term (Sub-study safety analysis set)

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	1 (3.3)	1 (3.3)
Generalised oedema	1 (3.3)	1 (3.3)

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-4-5s 2021-09-22 16:38

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

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177Lu-PSMA-617 SCS update

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Table 2-1-4-6 Randomized treatment-emergent adverse events leading to reduction of BSC/BSoC by preferred term (FAS safety set)

Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	17 (3.2)	0	7 (3.4)	0	24 (3.3)	0	17 (3.2)	0	7 (3.4)	0	24 (3.3)	0
Fatigue	8 (1.5)	0	2 (1.0)	0	10 (1.4)	0	8 (1.5)	0	2 (1.0)	0	10 (1.4)	0
Asthenia	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Blood creatinine increased	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Cognitive disorder	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Confusional state	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Decubitus ulcer	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Dry eye	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Fall	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Nausea	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0	1 (0.2)	0	1 (0.5)	0	2 (0.3)	0
Stomatitis	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Throat irritation	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Vomiting	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	0	0	0	1 (0.1)	0
Alanine aminotransferase increased	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Arthralgia	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Aspartate aminotransferase increased	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Decreased appetite	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Disturbance in attention	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Dyspnoea	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

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Preferred term	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Oedema peripheral	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0
Transaminases increased	0	0	1 (0.5)	0	1 (0.1)	0	0	0	1 (0.5)	0	1 (0.1)	0

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the Safety Update 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Output ID: T-2-1-4-6 2021-09-22 16:38

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Source data: adsl.xpt, adae.xpt

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177Lu-PSMA-617 SCS update

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Table 2-1-4-6s Study treatment-emergent adverse events leading to reduction of BSC/BSoC by preferred term (Sub-study safety analysis set)

Preferred term	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Number of patients with at least one event	1 (3.3)	0
Depressed mood	1 (3.3)	0

A patient with multiple grades for a preferred term is only counted under the maximum grade.

Preferred terms are sorted in descending frequency of 'All Grades' column, as reported in the 'Lu-PSMA-617+BSC/BSoC' column.

Coded using MedDRA version 24.0 and CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-4-6s 2021-09-22 16:39

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Source data: adsl.xpt, adae.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-5-1 Overview of randomized treatment-emergent safety topics of interest (FAS safety set)

Safety topic	Original submission: 27-Jan-2021 data cut-off						Safety Update: 28-Jun-2021 data cut-off					
	Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)		Lu-PSMA-617 +BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)	All grades n (%)	Grade >=3 n (%)
Fatigue	260 (49.1)	37 (7.0)	60 (29.3)	5 (2.4)	320 (43.6)	42 (5.7)	260 (49.1)	37 (7.0)	60 (29.3)	5 (2.4)	320 (43.6)	42 (5.7)
Myelosuppression	251 (47.4)	124 (23.4)	36 (17.6)	14 (6.8)	287 (39.1)	138 (18.8)	251 (47.4)	124 (23.4)	36 (17.6)	14 (6.8)	287 (39.1)	138 (18.8)
Nausea and Vomiting*	208 (39.3)	8 (1.5)	35 (17.1)	1 (0.5)	243 (33.1)	9 (1.2)	209 (39.5)	8 (1.5)	35 (17.1)	1 (0.5)	244 (33.2)	9 (1.2)
Dry mouth	208 (39.3)	0	2 (1.0)	0	210 (28.6)	0	208 (39.3)	0	2 (1.0)	0	210 (28.6)	0
Hypersensitivity*	55 (10.4)	5 (0.9)	7 (3.4)	0	62 (8.4)	5 (0.7)	56 (10.6)	5 (0.9)	7 (3.4)	0	63 (8.6)	5 (0.7)
Hepatotoxicity	54 (10.2)	15 (2.8)	16 (7.8)	5 (2.4)	70 (9.5)	20 (2.7)	54 (10.2)	15 (2.8)	16 (7.8)	5 (2.4)	70 (9.5)	20 (2.7)
Renal toxicity	46 (8.7)	18 (3.4)	12 (5.9)	6 (2.9)	58 (7.9)	24 (3.3)	46 (8.7)	18 (3.4)	12 (5.9)	6 (2.9)	58 (7.9)	24 (3.3)
Late renal toxicity	25 (4.7)	12 (2.3)	2 (1.0)	1 (0.5)	27 (3.7)	13 (1.8)	25 (4.7)	12 (2.3)	2 (1.0)	1 (0.5)	27 (3.7)	13 (1.8)
Second primary malignancies*	11 (2.1)	4 (0.8)	2 (1.0)	1 (0.5)	13 (1.8)	5 (0.7)	12 (2.3)	5 (0.9)	2 (1.0)	1 (0.5)	14 (1.9)	6 (0.8)
QT prolongation	9 (1.7)	7 (1.3)	1 (0.5)	1 (0.5)	10 (1.4)	8 (1.1)	9 (1.7)	7 (1.3)	1 (0.5)	1 (0.5)	10 (1.4)	8 (1.1)
Intracranial haemorrhage	7 (1.3)	5 (0.9)	3 (1.5)	2 (1.0)	10 (1.4)	7 (1.0)	7 (1.3)	5 (0.9)	3 (1.5)	2 (1.0)	10 (1.4)	7 (1.0)
Medication errors	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
Radiotoxicity including inadvertent exposure	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)	1 (0.2)	1 (0.2)	1 (0.5)	0	2 (0.3)	1 (0.1)
Reproductive toxicity	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment.

A patient with multiple grades for a safety topic is only counted under the maximum grade.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-5-1 2021-09-22 16:40

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Source data: adsl.xpt, adrisk.xpt

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Table 2-1-5-1s Overview of study treatment-emergent safety topics of interest (Sub-study safety analysis set)

Safety topic	Lu-PSMA-617 +BSC/BSoC (N=30)	
	All grades n (%)	Grade >=3 n (%)
Myelosuppression	11 (36.7)	6 (20.0)
Nausea and Vomiting	11 (36.7)	0
Fatigue	6 (20.0)	2 (6.7)
Dry mouth	5 (16.7)	0
Renal toxicity	5 (16.7)	0
Hypersensitivity	3 (10.0)	1 (3.3)
Hepatotoxicity	2 (6.7)	0
Late renal toxicity	2 (6.7)	0
Intracranial haemorrhage	0	0
Medication errors	0	0
QT prolongation	0	0
Radiotoxicity including inadvertent exposure	0	0
Reproductive toxicity	0	0
Second primary malignancies	0	0

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment.

A patient with multiple grades for a safety topic is only counted under the maximum grade.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-5-1s 2021-09-22 16:40

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-5-2 Incidence of randomized treatment-emergent safety topics of interest (FAS safety set)

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Fatigue						
Number of patients with at least one event	260 (49.1)	60 (29.3)	320 (43.6)	260 (49.1)	60 (29.3)	320 (43.6)
Maximum grade						
Grade 3 AEs	37 (7.0)	4 (2.0)	41 (5.6)	37 (7.0)	4 (2.0)	41 (5.6)
Grade 4 AEs	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	190 (35.9)	23 (11.2)	213 (29.0)	190 (35.9)	23 (11.2)	213 (29.0)
SAEs	4 (0.8)	1 (0.5)	5 (0.7)	4 (0.8)	1 (0.5)	5 (0.7)
Action taken with PSMA-617						
Drug withdrawn	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Dose reduced	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Drug interrupted	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Dose not changed/NA/unknown	258 (48.8)	60 (29.3)	318 (43.3)	258 (48.8)	60 (29.3)	318 (43.3)
Action taken with BSC/BSoC						
Drug withdrawn	5 (0.9)	0	5 (0.7)	5 (0.9)	0	5 (0.7)
Dose reduced	9 (1.7)	3 (1.5)	12 (1.6)	9 (1.7)	3 (1.5)	12 (1.6)
Drug interrupted	2 (0.4)	1 (0.5)	3 (0.4)	2 (0.4)	1 (0.5)	3 (0.4)
Dose not changed/NA/unknown	248 (46.9)	56 (27.3)	304 (41.4)	248 (46.9)	56 (27.3)	304 (41.4)
AE outcome						
Recovered/resolved	98 (18.5)	9 (4.4)	107 (14.6)	98 (18.5)	9 (4.4)	107 (14.6)
Recovering/resolving	7 (1.3)	3 (1.5)	10 (1.4)	7 (1.3)	3 (1.5)	10 (1.4)
Not recovered/not resolved*	179 (33.8)	54 (26.3)	233 (31.7)	179 (33.8)	53 (25.9)	232 (31.6)
Recovered/resolved with sequelae	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Fatal	0	0	0	0	0	0
Unknown	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)

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177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Myelosuppression						
Number of patients with at least one event	251 (47.4)	36 (17.6)	287 (39.1)	251 (47.4)	36 (17.6)	287 (39.1)
Maximum grade						
Grade 3 AEs	104 (19.7)	14 (6.8)	118 (16.1)	104 (19.7)	14 (6.8)	118 (16.1)
Grade 4 AEs	17 (3.2)	0	17 (2.3)	17 (3.2)	0	17 (2.3)
Grade 5 AEs	3 (0.6)	0	3 (0.4)	3 (0.6)	0	3 (0.4)
Treatment-related AEs	215 (40.6)	10 (4.9)	225 (30.7)	215 (40.6)	10 (4.9)	225 (30.7)
SAEs	27 (5.1)	1 (0.5)	28 (3.8)	27 (5.1)	1 (0.5)	28 (3.8)
Action taken with PSMA-617						
Drug withdrawn	37 (7.0)	1 (0.5)	38 (5.2)	37 (7.0)	1 (0.5)	38 (5.2)
Dose reduced	21 (4.0)	0	21 (2.9)	21 (4.0)	0	21 (2.9)
Drug interrupted	50 (9.5)	1 (0.5)	51 (6.9)	50 (9.5)	1 (0.5)	51 (6.9)
Dose not changed/NA/unknown	233 (44.0)	36 (17.6)	269 (36.6)	233 (44.0)	36 (17.6)	269 (36.6)
Action taken with BSC/BSoC						
Drug withdrawn	14 (2.6)	0	14 (1.9)	14 (2.6)	0	14 (1.9)
Dose reduced	0	0	0	0	0	0
Drug interrupted	12 (2.3)	0	12 (1.6)	12 (2.3)	0	12 (1.6)
Dose not changed/NA/unknown	246 (46.5)	36 (17.6)	282 (38.4)	246 (46.5)	36 (17.6)	282 (38.4)
AE outcome						
Recovered/resolved*	123 (23.3)	16 (7.8)	139 (18.9)	123 (23.3)	17 (8.3)	140 (19.1)
Recovering/resolving	4 (0.8)	1 (0.5)	5 (0.7)	4 (0.8)	1 (0.5)	5 (0.7)
Not recovered/not resolved	188 (35.5)	26 (12.7)	214 (29.2)	188 (35.5)	26 (12.7)	214 (29.2)
Recovered/resolved with sequelae	3 (0.6)	0	3 (0.4)	3 (0.6)	0	3 (0.4)
Fatal	3 (0.6)	0	3 (0.4)	3 (0.6)	0	3 (0.4)
Unknown	3 (0.6)	0	3 (0.4)	3 (0.6)	0	3 (0.4)
Nausea and Vomiting						

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177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Safety Update: 28-Jun-2021 data cut-off Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Number of patients with at least one event*	208 (39.3)	35 (17.1)	243 (33.1)	209 (39.5)	35 (17.1)	244 (33.2)
Maximum grade						
Grade 3 AEs	8 (1.5)	1 (0.5)	9 (1.2)	8 (1.5)	1 (0.5)	9 (1.2)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	162 (30.6)	9 (4.4)	171 (23.3)	162 (30.6)	9 (4.4)	171 (23.3)
SAEs	5 (0.9)	1 (0.5)	6 (0.8)	5 (0.9)	1 (0.5)	6 (0.8)
Action taken with PSMA-617						
Drug withdrawn	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown*	207 (39.1)	35 (17.1)	242 (33.0)	208 (39.3)	35 (17.1)	243 (33.1)
Action taken with BSC/BSoC						
Drug withdrawn	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Dose reduced	2 (0.4)	1 (0.5)	3 (0.4)	2 (0.4)	1 (0.5)	3 (0.4)
Drug interrupted	3 (0.6)	1 (0.5)	4 (0.5)	3 (0.6)	1 (0.5)	4 (0.5)
Dose not changed/NA/unknown*	207 (39.1)	33 (16.1)	240 (32.7)	208 (39.3)	33 (16.1)	241 (32.8)
AE outcome						
Recovered/resolved	153 (28.9)	23 (11.2)	176 (24.0)	153 (28.9)	23 (11.2)	176 (24.0)
Recovering/resolving	3 (0.6)	1 (0.5)	4 (0.5)	3 (0.6)	1 (0.5)	4 (0.5)
Not recovered/not resolved	78 (14.7)	18 (8.8)	96 (13.1)	78 (14.7)	18 (8.8)	96 (13.1)
Recovered/resolved with sequelae	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Fatal	0	0	0	0	0	0
Unknown	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Dry mouth						
Number of patients with at least one event	208 (39.3)	2 (1.0)	210 (28.6)	208 (39.3)	2 (1.0)	210 (28.6)

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177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Maximum grade						
Grade 3 AEs	0	0	0	0	0	0
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	194 (36.7)	1 (0.5)	195 (26.6)	194 (36.7)	1 (0.5)	195 (26.6)
SAEs	0	0	0	0	0	0
Action taken with PSMA-617						
Drug withdrawn	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose reduced	3 (0.6)	0	3 (0.4)	3 (0.6)	0	3 (0.4)
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	205 (38.8)	2 (1.0)	207 (28.2)	205 (38.8)	2 (1.0)	207 (28.2)
Action taken with BSC/BSoC						
Drug withdrawn	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	207 (39.1)	2 (1.0)	209 (28.5)	207 (39.1)	2 (1.0)	209 (28.5)
AE outcome						
Recovered/resolved*	70 (13.2)	1 (0.5)	71 (9.7)	71 (13.4)	1 (0.5)	72 (9.8)
Recovering/resolving	8 (1.5)	0	8 (1.1)	8 (1.5)	0	8 (1.1)
Not recovered/not resolved*	138 (26.1)	2 (1.0)	140 (19.1)	137 (25.9)	2 (1.0)	139 (18.9)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	4 (0.8)	0	4 (0.5)	4 (0.8)	0	4 (0.5)
Hypersensitivity						
Number of patients with at least one event*	55 (10.4)	7 (3.4)	62 (8.4)	56 (10.6)	7 (3.4)	63 (8.6)
Maximum grade						

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Grade 3 AEs	5 (0.9)	0	5 (0.7)	5 (0.9)	0	5 (0.7)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	20 (3.8)	0	20 (2.7)	20 (3.8)	0	20 (2.7)
SAEs	3 (0.6)	0	3 (0.4)	3 (0.6)	0	3 (0.4)
Action taken with PSMA-617						
Drug withdrawn	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown*	54 (10.2)	7 (3.4)	61 (8.3)	55 (10.4)	7 (3.4)	62 (8.4)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown*	55 (10.4)	7 (3.4)	62 (8.4)	56 (10.6)	7 (3.4)	63 (8.6)
AE outcome						
Recovered/resolved*	37 (7.0)	5 (2.4)	42 (5.7)	38 (7.2)	5 (2.4)	43 (5.9)
Recovering/resolving	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Not recovered/not resolved	20 (3.8)	3 (1.5)	23 (3.1)	20 (3.8)	3 (1.5)	23 (3.1)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Hepatotoxicity						
Number of patients with at least one event	54 (10.2)	16 (7.8)	70 (9.5)	54 (10.2)	16 (7.8)	70 (9.5)
Maximum grade						
Grade 3 AEs	11 (2.1)	5 (2.4)	16 (2.2)	11 (2.1)	5 (2.4)	16 (2.2)
Grade 4 AEs	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
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Grade 5 AEs	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Treatment-related AEs	21 (4.0)	6 (2.9)	27 (3.7)	21 (4.0)	6 (2.9)	27 (3.7)
SAEs	5 (0.9)	2 (1.0)	7 (1.0)	5 (0.9)	2 (1.0)	7 (1.0)
Action taken with PSMA-617						
Drug withdrawn	3 (0.6)	1 (0.5)	4 (0.5)	3 (0.6)	1 (0.5)	4 (0.5)
Dose reduced	0	0	0	0	0	0
Drug interrupted	4 (0.8)	1 (0.5)	5 (0.7)	4 (0.8)	1 (0.5)	5 (0.7)
Dose not changed/NA/unknown	53 (10.0)	16 (7.8)	69 (9.4)	53 (10.0)	16 (7.8)	69 (9.4)
Action taken with BSC/BSoC						
Drug withdrawn	5 (0.9)	1 (0.5)	6 (0.8)	5 (0.9)	1 (0.5)	6 (0.8)
Dose reduced	0	2 (1.0)	2 (0.3)	0	2 (1.0)	2 (0.3)
Drug interrupted	5 (0.9)	3 (1.5)	8 (1.1)	5 (0.9)	3 (1.5)	8 (1.1)
Dose not changed/NA/unknown	50 (9.5)	11 (5.4)	61 (8.3)	50 (9.5)	11 (5.4)	61 (8.3)
AE outcome						
Recovered/resolved	31 (5.9)	7 (3.4)	38 (5.2)	31 (5.9)	7 (3.4)	38 (5.2)
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	30 (5.7)	10 (4.9)	40 (5.4)	30 (5.7)	10 (4.9)	40 (5.4)
Recovered/resolved with sequelae	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Fatal	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Unknown	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Renal toxicity						
Number of patients with at least one event	46 (8.7)	12 (5.9)	58 (7.9)	46 (8.7)	12 (5.9)	58 (7.9)
Maximum grade						
Grade 3 AEs	18 (3.4)	6 (2.9)	24 (3.3)	18 (3.4)	6 (2.9)	24 (3.3)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
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Treatment-related AEs	18 (3.4)	0	18 (2.5)	18 (3.4)	0	18 (2.5)
SAEs	9 (1.7)	7 (3.4)	16 (2.2)	9 (1.7)	7 (3.4)	16 (2.2)
Action taken with PSMA-617						
Drug withdrawn	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose reduced	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Drug interrupted	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Dose not changed/NA/unknown	42 (7.9)	12 (5.9)	54 (7.4)	42 (7.9)	12 (5.9)	54 (7.4)
Action taken with BSC/BSoC						
Drug withdrawn	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Dose reduced	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Drug interrupted	1 (0.2)	2 (1.0)	3 (0.4)	1 (0.2)	2 (1.0)	3 (0.4)
Dose not changed/NA/unknown	44 (8.3)	10 (4.9)	54 (7.4)	44 (8.3)	10 (4.9)	54 (7.4)
AE outcome						
Recovered/resolved	29 (5.5)	8 (3.9)	37 (5.0)	29 (5.5)	8 (3.9)	37 (5.0)
Recovering/resolving	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
Not recovered/not resolved	18 (3.4)	3 (1.5)	21 (2.9)	18 (3.4)	3 (1.5)	21 (2.9)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
Late renal toxicity						
Number of patients with at least one event	25 (4.7)	2 (1.0)	27 (3.7)	25 (4.7)	2 (1.0)	27 (3.7)
Maximum grade						
Grade 3 AEs	12 (2.3)	1 (0.5)	13 (1.8)	12 (2.3)	1 (0.5)	13 (1.8)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	10 (1.9)	0	10 (1.4)	10 (1.9)	0	10 (1.4)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
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SAEs	7 (1.3)	1 (0.5)	8 (1.1)	7 (1.3)	1 (0.5)	8 (1.1)
Action taken with PSMA-617						
Drug withdrawn	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0	0	0	0
Drug interrupted	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	23 (4.3)	2 (1.0)	25 (3.4)	23 (4.3)	2 (1.0)	25 (3.4)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	25 (4.7)	2 (1.0)	27 (3.7)	25 (4.7)	2 (1.0)	27 (3.7)
AE outcome						
Recovered/resolved	16 (3.0)	1 (0.5)	17 (2.3)	16 (3.0)	1 (0.5)	17 (2.3)
Recovering/resolving	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Not recovered/not resolved	9 (1.7)	1 (0.5)	10 (1.4)	9 (1.7)	1 (0.5)	10 (1.4)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0
Second primary malignancies						
Number of patients with at least one event*	11 (2.1)	2 (1.0)	13 (1.8)	12 (2.3)	2 (1.0)	14 (1.9)
Maximum grade						
Grade 3 AEs	3 (0.6)	1 (0.5)	4 (0.5)	3 (0.6)	1 (0.5)	4 (0.5)
Grade 4 AEs*	0	0	0	1 (0.2)	0	1 (0.1)
Grade 5 AEs	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Treatment-related AEs	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
SAEs*	3 (0.6)	0	3 (0.4)	4 (0.8)	0	4 (0.5)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
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Action taken with PSMA-617						
Drug withdrawn	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown*	10 (1.9)	2 (1.0)	12 (1.6)	11 (2.1)	2 (1.0)	13 (1.8)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown*	11 (2.1)	2 (1.0)	13 (1.8)	12 (2.3)	2 (1.0)	14 (1.9)
AE outcome						
Recovered/resolved	4 (0.8)	2 (1.0)	6 (0.8)	4 (0.8)	2 (1.0)	6 (0.8)
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved*	4 (0.8)	0	4 (0.5)	5 (0.9)	0	5 (0.7)
Recovered/resolved with sequelae	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Fatal	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Unknown	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
QT prolongation						
Number of patients with at least one event	9 (1.7)	1 (0.5)	10 (1.4)	9 (1.7)	1 (0.5)	10 (1.4)
Maximum grade						
Grade 3 AEs	7 (1.3)	0	7 (1.0)	7 (1.3)	0	7 (1.0)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Treatment-related AEs	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
SAEs	6 (1.1)	1 (0.5)	7 (1.0)	6 (1.1)	1 (0.5)	7 (1.0)
Action taken with PSMA-617						
Drug withdrawn	0	0	0	0	0	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
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Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	9 (1.7)	1 (0.5)	10 (1.4)	9 (1.7)	1 (0.5)	10 (1.4)
Action taken with BSC/BSoC						
Drug withdrawn	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	8 (1.5)	1 (0.5)	9 (1.2)	8 (1.5)	1 (0.5)	9 (1.2)
AE outcome						
Recovered/resolved	9 (1.7)	0	9 (1.2)	9 (1.7)	0	9 (1.2)
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	0	0	0	0	0	0
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	1 (0.5)	1 (0.1)	0	1 (0.5)	1 (0.1)
Unknown	0	0	0	0	0	0
Intracranial haemorrhage						
Number of patients with at least one event	7 (1.3)	3 (1.5)	10 (1.4)	7 (1.3)	3 (1.5)	10 (1.4)
Maximum grade						
Grade 3 AEs	3 (0.6)	1 (0.5)	4 (0.5)	3 (0.6)	1 (0.5)	4 (0.5)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	2 (0.4)	1 (0.5)	3 (0.4)	2 (0.4)	1 (0.5)	3 (0.4)
Treatment-related AEs	3 (0.6)	0	3 (0.4)	3 (0.6)	0	3 (0.4)
SAEs	7 (1.3)	2 (1.0)	9 (1.2)	7 (1.3)	2 (1.0)	9 (1.2)
Action taken with PSMA-617						
Drug withdrawn	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
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Dose not changed/NA/unknown	6 (1.1)	3 (1.5)	9 (1.2)	6 (1.1)	3 (1.5)	9 (1.2)
Action taken with BSC/BSoC						
Drug withdrawn	2 (0.4)	0	2 (0.3)	2 (0.4)	0	2 (0.3)
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	5 (0.9)	3 (1.5)	8 (1.1)	5 (0.9)	3 (1.5)	8 (1.1)
AE outcome						
Recovered/resolved	2 (0.4)	1 (0.5)	3 (0.4)	2 (0.4)	1 (0.5)	3 (0.4)
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	3 (0.6)	1 (0.5)	4 (0.5)	3 (0.6)	1 (0.5)	4 (0.5)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	2 (0.4)	1 (0.5)	3 (0.4)	2 (0.4)	1 (0.5)	3 (0.4)
Unknown	0	0	0	0	0	0
Medication errors						
Number of patients with at least one event	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Maximum grade						
Grade 3 AEs	0	0	0	0	0	0
Grade 4 AEs	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	0	0	0	0	0	0
SAEs	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
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Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
AE outcome						
Recovered/resolved	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	0	0	0	0	0	0
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0
Radiotoxicity including inadvertent exposure						
Number of patients with at least one event	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
Maximum grade						
Grade 3 AEs	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	0	0	0	0	0	0
SAEs	0	0	0	0	0	0
Action taken with PSMA-617						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

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Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
AE outcome						
Recovered/resolved	1 (0.2)	1 (0.5)	2 (0.3)	1 (0.2)	1 (0.5)	2 (0.3)
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	0	0	0	0	0	0
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0
Reproductive toxicity						
Number of patients with at least one event	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Maximum grade						
Grade 3 AEs	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	0	0	0	0	0	0
SAEs	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Original submission: 27-Jan-2021 data cut-off			Safety Update: 28-Jun-2021 data cut-off		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
AE outcome						
Recovered/resolved	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	0	0	0	0	0	0
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment.

A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

*Indicates a change between the Safety Update and the Original Submission.

Output ID: T-2-1-5-2 2021-09-22 23:43

...\\BIOMETRYPROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGMlt-aesi2.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Table 2-1-5-2s Incidence of study treatment-emergent safety topics of interest (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Myelosuppression	
Number of patients with at least one event	11 (36.7)
Maximum grade	
Grade 3 AEs	4 (13.3)
Grade 4 AEs	2 (6.7)
Grade 5 AEs	0
Treatment-related AEs	9 (30.0)
SAEs	3 (10.0)
Action taken with PSMA-617	
Drug withdrawn	2 (6.7)
Dose reduced	2 (6.7)
Drug interrupted	2 (6.7)
Dose not changed/NA/unknown	10 (33.3)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	11 (36.7)
AE outcome	
Recovered/resolved	3 (10.0)
Recovering/resolving	0
Not recovered/not resolved	9 (30.0)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	1 (3.3)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Nausea and Vomiting	
Number of patients with at least one event	11 (36.7)
Maximum grade	
Grade 3 AEs	0
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	7 (23.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	11 (36.7)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	11 (36.7)
AE outcome	
Recovered/resolved	8 (26.7)
Recovering/resolving	0
Not recovered/not resolved	4 (13.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0
Fatigue	
Number of patients with at least one event	6 (20.0)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Maximum grade	
Grade 3 AEs	2 (6.7)
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	4 (13.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	6 (20.0)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	6 (20.0)
AE outcome	
Recovered/resolved	0
Recovering/resolving	1 (3.3)
Not recovered/not resolved	5 (16.7)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0
Dry mouth	
Number of patients with at least one event	5 (16.7)
Maximum grade	
Grade 3 AEs	0

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Final Version

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	4 (13.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	5 (16.7)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	5 (16.7)
AE outcome	
Recovered/resolved	1 (3.3)
Recovering/resolving	0
Not recovered/not resolved	4 (13.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0
Renal toxicity	
Number of patients with at least one event	5 (16.7)
Maximum grade	
Grade 3 AEs	0
Grade 4 AEs	0
Grade 5 AEs	0

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Final Version

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Treatment-related AEs	4 (13.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	5 (16.7)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	5 (16.7)
AE outcome	
Recovered/resolved	1 (3.3)
Recovering/resolving	0
Not recovered/not resolved	4 (13.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0
Hypersensitivity	
Number of patients with at least one event	3 (10.0)
Maximum grade	
Grade 3 AEs	1 (3.3)
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	1 (3.3)
SAEs	0

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	1 (3.3)
Dose not changed/NA/unknown	3 (10.0)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	1 (3.3)
Dose not changed/NA/unknown	3 (10.0)
AE outcome	
Recovered/resolved	2 (6.7)
Recovering/resolving	0
Not recovered/not resolved	2 (6.7)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0
Hepatotoxicity	
Number of patients with at least one event	2 (6.7)
Maximum grade	
Grade 3 AEs	0
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	1 (3.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	2 (6.7)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	2 (6.7)
AE outcome	
Recovered/resolved	2 (6.7)
Recovering/resolving	0
Not recovered/not resolved	1 (3.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	1 (3.3)
Late renal toxicity	
Number of patients with at least one event	2 (6.7)
Maximum grade	
Grade 3 AEs	0
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	2 (6.7)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	2 (6.7)

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Action taken with BSC/BSoC	0
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	2 (6.7)
AE outcome	0
Recovered/resolved	0
Recovering/resolving	0
Not recovered/not resolved	2 (6.7)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment.

A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-2-1-5-2s 2021-09-23 00:02

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Fatigue			
Number of patients with at least one event	260 (49.1)	60 (29.3)	320 (43.6)
Fatigue	228 (43.1)	47 (22.9)	275 (37.5)
Asthenia	34 (6.4)	16 (7.8)	50 (6.8)
Malaise	13 (2.5)	1 (0.5)	14 (1.9)
Lethargy	3 (0.6)	0	3 (0.4)
Cachexia	2 (0.4)	0	2 (0.3)
Decreased activity	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	37 (7.0)	4 (2.0)	41 (5.6)
Fatigue	31 (5.9)	3 (1.5)	34 (4.6)
Asthenia	6 (1.1)	1 (0.5)	7 (1.0)
Cachexia	1 (0.2)	0	1 (0.1)
Malaise	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	1 (0.5)	1 (0.1)
Asthenia	0	1 (0.5)	1 (0.1)
Grade 5 AEs	0	0	0
Treatment-related AEs	190 (35.9)	23 (11.2)	213 (29.0)
Fatigue	165 (31.2)	14 (6.8)	179 (24.4)
Asthenia	24 (4.5)	10 (4.9)	34 (4.6)
Malaise	9 (1.7)	1 (0.5)	10 (1.4)
Lethargy	1 (0.2)	0	1 (0.1)
SAEs	4 (0.8)	1 (0.5)	5 (0.7)
Fatigue	2 (0.4)	0	2 (0.3)
Cachexia	1 (0.2)	0	1 (0.1)
Malaise	1 (0.2)	0	1 (0.1)
Asthenia	0	1 (0.5)	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	2 (0.4)	0	2 (0.3)
Fatigue	2 (0.4)	0	2 (0.3)
Dose reduced	2 (0.4)	0	2 (0.3)
Fatigue	2 (0.4)	0	2 (0.3)
Drug interrupted	2 (0.4)	0	2 (0.3)
Asthenia	1 (0.2)	0	1 (0.1)
Fatigue	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	258 (48.8)	60 (29.3)	318 (43.3)
Fatigue	226 (42.7)	47 (22.9)	273 (37.2)
Asthenia	33 (6.2)	16 (7.8)	49 (6.7)
Malaise	13 (2.5)	1 (0.5)	14 (1.9)
Lethargy	3 (0.6)	0	3 (0.4)
Cachexia	2 (0.4)	0	2 (0.3)
Decreased activity	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	5 (0.9)	0	5 (0.7)
Fatigue	5 (0.9)	0	5 (0.7)
Asthenia	1 (0.2)	0	1 (0.1)
Dose reduced	9 (1.7)	3 (1.5)	12 (1.6)

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Fatigue	8 (1.5)	2 (1.0)	10 (1.4)
Asthenia	1 (0.2)	1 (0.5)	2 (0.3)
Drug interrupted	2 (0.4)	1 (0.5)	3 (0.4)
Fatigue	2 (0.4)	1 (0.5)	3 (0.4)
Dose not changed/NA/unknown	248 (46.9)	56 (27.3)	304 (41.4)
Fatigue	216 (40.8)	44 (21.5)	260 (35.4)
Asthenia	33 (6.2)	15 (7.3)	48 (6.5)
Malaise	13 (2.5)	1 (0.5)	14 (1.9)
Lethargy	3 (0.6)	0	3 (0.4)
Cachexia	2 (0.4)	0	2 (0.3)
Decreased activity	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	98 (18.5)	9 (4.4)	107 (14.6)
Fatigue	75 (14.2)	4 (2.0)	79 (10.8)
Asthenia	14 (2.6)	4 (2.0)	18 (2.5)
Malaise	10 (1.9)	1 (0.5)	11 (1.5)
Lethargy	2 (0.4)	0	2 (0.3)
Recovering/resolving	7 (1.3)	3 (1.5)	10 (1.4)
Fatigue	5 (0.9)	2 (1.0)	7 (1.0)
Asthenia	2 (0.4)	1 (0.5)	3 (0.4)
Not recovered/not resolved	179 (33.8)	53 (25.9)	232 (31.6)
Fatigue	161 (30.4)	43 (21.0)	204 (27.8)
Asthenia	20 (3.8)	12 (5.9)	32 (4.4)
Cachexia	2 (0.4)	0	2 (0.3)
Malaise	2 (0.4)	0	2 (0.3)
Decreased activity	1 (0.2)	0	1 (0.1)
Lethargy	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	1 (0.2)	0	1 (0.1)
Malaise	1 (0.2)	0	1 (0.1)
Fatal	0	0	0
Unknown	1 (0.2)	0	1 (0.1)
Fatigue	1 (0.2)	0	1 (0.1)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:26

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aes13.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Myelosuppression			
Number of patients with at least one event	251 (47.4)	36 (17.6)	287 (39.1)
Anaemia	168 (31.8)	27 (13.2)	195 (26.6)
Thrombocytopenia	91 (17.2)	9 (4.4)	100 (13.6)
Lymphopenia	75 (14.2)	8 (3.9)	83 (11.3)
Leukopenia	66 (12.5)	4 (2.0)	70 (9.5)
Neutropenia	45 (8.5)	3 (1.5)	48 (6.5)
Pancytopenia	8 (1.5)	0	8 (1.1)
Febrile neutropenia	2 (0.4)	0	2 (0.3)
Bicytopenia	1 (0.2)	0	1 (0.1)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Normocytic anaemia	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	104 (19.7)	14 (6.8)	118 (16.1)
Anaemia	55 (10.4)	10 (4.9)	65 (8.9)
Lymphopenia	35 (6.6)	1 (0.5)	36 (4.9)
Thrombocytopenia	27 (5.1)	2 (1.0)	29 (4.0)
Neutropenia	11 (2.1)	1 (0.5)	12 (1.6)
Leukopenia	8 (1.5)	1 (0.5)	9 (1.2)
Pancytopenia	2 (0.4)	0	2 (0.3)
Bicytopenia	1 (0.2)	0	1 (0.1)
Grade 4 AEs	17 (3.2)	0	17 (2.3)
Thrombocytopenia	10 (1.9)	0	10 (1.4)
Lymphopenia	3 (0.6)	0	3 (0.4)
Leukopenia	2 (0.4)	0	2 (0.3)
Pancytopenia	2 (0.4)	0	2 (0.3)
Anaemia	1 (0.2)	0	1 (0.1)
Neutropenia	1 (0.2)	0	1 (0.1)
Grade 5 AEs	3 (0.6)	0	3 (0.4)
Pancytopenia	2 (0.4)	0	2 (0.3)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Treatment-related AEs			
Anaemia	215 (40.6)	10 (4.9)	225 (30.7)
Thrombocytopenia	135 (25.5)	6 (2.9)	141 (19.2)
Lymphopenia	83 (15.7)	0	83 (11.3)
Leukopenia	61 (11.5)	2 (1.0)	63 (8.6)
Neutropenia	58 (11.0)	3 (1.5)	61 (8.3)
Pancytopenia	43 (8.1)	2 (1.0)	45 (6.1)
Bicytopenia	6 (1.1)	0	6 (0.8)
Febrile neutropenia	1 (0.2)	0	1 (0.1)
Bone marrow failure	1 (0.2)	0	1 (0.1)
SAEs	27 (5.1)	1 (0.5)	28 (3.8)
Anaemia	15 (2.8)	1 (0.5)	16 (2.2)
Pancytopenia	6 (1.1)	0	6 (0.8)
Thrombocytopenia	3 (0.6)	0	3 (0.4)
Leukopenia	2 (0.4)	0	2 (0.3)
Neutropenia	2 (0.4)	0	2 (0.3)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Febrile neutropenia	1 (0.2)	0	1 (0.1)

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	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Action taken with PSMA-617			
Drug withdrawn	37 (7.0)	1 (0.5)	38 (5.2)
Anaemia	15 (2.8)	1 (0.5)	16 (2.2)
Thrombocytopenia	15 (2.8)	0	15 (2.0)
Leukopenia	7 (1.3)	0	7 (1.0)
Neutropenia	4 (0.8)	0	4 (0.5)
Pancytopenia	3 (0.6)	0	3 (0.4)
Lymphopenia	2 (0.4)	0	2 (0.3)
Dose reduced	21 (4.0)	0	21 (2.9)
Thrombocytopenia	10 (1.9)	0	10 (1.4)
Anaemia	7 (1.3)	0	7 (1.0)
Leukopenia	3 (0.6)	0	3 (0.4)
Neutropenia	3 (0.6)	0	3 (0.4)
Lymphopenia	2 (0.4)	0	2 (0.3)
Drug interrupted	50 (9.5)	1 (0.5)	51 (6.9)
Anaemia	27 (5.1)	1 (0.5)	28 (3.8)
Thrombocytopenia	19 (3.6)	0	19 (2.6)
Leukopenia	8 (1.5)	0	8 (1.1)
Neutropenia	4 (0.8)	0	4 (0.5)
Lymphopenia	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	233 (44.0)	36 (17.6)	269 (36.6)
Anaemia	151 (28.5)	26 (12.7)	177 (24.1)
Thrombocytopenia	79 (14.9)	9 (4.4)	88 (12.0)
Lymphopenia	73 (13.8)	8 (3.9)	81 (11.0)
Leukopenia	59 (11.2)	4 (2.0)	63 (8.6)
Neutropenia	42 (7.9)	3 (1.5)	45 (6.1)
Pancytopenia	5 (0.9)	0	5 (0.7)
Febrile neutropenia	2 (0.4)	0	2 (0.3)
Bicytopenia	1 (0.2)	0	1 (0.1)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Normocytic anaemia	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	14 (2.6)	0	14 (1.9)
Anaemia	5 (0.9)	0	5 (0.7)
Thrombocytopenia	5 (0.9)	0	5 (0.7)
Leukopenia	2 (0.4)	0	2 (0.3)
Pancytopenia	2 (0.4)	0	2 (0.3)
Dose reduced	0	0	0
Drug interrupted	12 (2.3)	0	12 (1.6)
Anaemia	9 (1.7)	0	9 (1.2)
Thrombocytopenia	3 (0.6)	0	3 (0.4)
Lymphopenia	2 (0.4)	0	2 (0.3)
Leukopenia	1 (0.2)	0	1 (0.1)
Pancytopenia	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	246 (46.5)	36 (17.6)	282 (38.4)
Anaemia	161 (30.4)	27 (13.2)	188 (25.6)
Thrombocytopenia	89 (16.8)	9 (4.4)	98 (13.4)
Lymphopenia	75 (14.2)	8 (3.9)	83 (11.3)
Leukopenia	64 (12.1)	4 (2.0)	68 (9.3)
Neutropenia	45 (8.5)	3 (1.5)	48 (6.5)
Pancytopenia	5 (0.9)	0	5 (0.7)
Febrile neutropenia	2 (0.4)	0	2 (0.3)
Bicytopenia	1 (0.2)	0	1 (0.1)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Normocytic anaemia	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
AE outcome			
Recovered/resolved	123 (23.3)	17 (8.3)	140 (19.1)
Anaemia	54 (10.2)	11 (5.4)	65 (8.9)
Leukopenia	46 (8.7)	1 (0.5)	47 (6.4)
Lymphopenia	35 (6.6)	5 (2.4)	40 (5.4)
Neutropenia	29 (5.5)	1 (0.5)	30 (4.1)
Thrombocytopenia	25 (4.7)	1 (0.5)	26 (3.5)
Febrile neutropenia	2 (0.4)	0	2 (0.3)
Pancytopenia	1 (0.2)	0	1 (0.1)
Recovering/resolving	4 (0.8)	1 (0.5)	5 (0.7)
Leukopenia	2 (0.4)	0	2 (0.3)
Anaemia	1 (0.2)	1 (0.5)	2 (0.3)
Lymphopenia	1 (0.2)	0	1 (0.1)
Neutropenia	1 (0.2)	0	1 (0.1)
Thrombocytopenia	1 (0.2)	0	1 (0.1)
Not recovered/not resolved	188 (35.5)	26 (12.7)	214 (29.2)
Anaemia	125 (23.6)	18 (8.8)	143 (19.5)
Thrombocytopenia	72 (13.6)	8 (3.9)	80 (10.9)
Lymphopenia	47 (8.9)	4 (2.0)	51 (6.9)
Leukopenia	24 (4.5)	3 (1.5)	27 (3.7)
Neutropenia	20 (3.8)	2 (1.0)	22 (3.0)
Pancytopenia	2 (0.4)	0	2 (0.3)
Bicytopenia	1 (0.2)	0	1 (0.1)
Normocytic anaemia	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	3 (0.6)	0	3 (0.4)
Anaemia	1 (0.2)	0	1 (0.1)
Neutropenia	1 (0.2)	0	1 (0.1)
Pancytopenia	1 (0.2)	0	1 (0.1)
Fatal	3 (0.6)	0	3 (0.4)
Pancytopenia	2 (0.4)	0	2 (0.3)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Unknown	3 (0.6)	0	3 (0.4)
Pancytopenia	2 (0.4)	0	2 (0.3)
Thrombocytopenia	1 (0.2)	0	1 (0.1)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:26

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Nausea and Vomiting			
Number of patients with at least one event	209 (39.5)	35 (17.1)	244 (33.2)
Nausea	188 (35.5)	34 (16.6)	222 (30.2)
Vomiting	100 (18.9)	13 (6.3)	113 (15.4)
Retching	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	8 (1.5)	1 (0.5)	9 (1.2)
Nausea	7 (1.3)	1 (0.5)	8 (1.1)
Vomiting	5 (0.9)	1 (0.5)	6 (0.8)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
Treatment-related AEs	162 (30.6)	9 (4.4)	171 (23.3)
Nausea	148 (28.0)	8 (3.9)	156 (21.3)
Vomiting	63 (11.9)	3 (1.5)	66 (9.0)
SAEs			
Vomiting	5 (0.9)	1 (0.5)	6 (0.8)
Nausea	5 (0.9)	1 (0.5)	6 (0.8)
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Vomiting	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	208 (39.3)	35 (17.1)	243 (33.1)
Nausea	188 (35.5)	34 (16.6)	222 (30.2)
Vomiting	99 (18.7)	13 (6.3)	112 (15.3)
Retching	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	1 (0.5)	1 (0.1)
Nausea	0	1 (0.5)	1 (0.1)
Dose reduced	2 (0.4)	1 (0.5)	3 (0.4)
Nausea	1 (0.2)	1 (0.5)	2 (0.3)
Vomiting	1 (0.2)	0	1 (0.1)
Drug interrupted	3 (0.6)	1 (0.5)	4 (0.5)
Nausea	3 (0.6)	1 (0.5)	4 (0.5)
Vomiting	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	208 (39.3)	33 (16.1)	241 (32.8)
Nausea	186 (35.2)	31 (15.1)	217 (29.6)
Vomiting	99 (18.7)	13 (6.3)	112 (15.3)
Retching	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	153 (28.9)	23 (11.2)	176 (24.0)
Nausea	123 (23.3)	18 (8.8)	141 (19.2)
Vomiting	79 (14.9)	11 (5.4)	90 (12.3)
Retching	1 (0.2)	0	1 (0.1)
Recovering/resolving	3 (0.6)	1 (0.5)	4 (0.5)
Nausea	3 (0.6)	1 (0.5)	4 (0.5)

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Not recovered/not resolved	78 (14.7)	18 (8.8)	96 (13.1)
Nausea	73 (13.8)	18 (8.8)	91 (12.4)
Vomiting	27 (5.1)	2 (1.0)	29 (4.0)
Recovered/resolved with sequelae	1 (0.2)	0	1 (0.1)
Nausea	1 (0.2)	0	1 (0.1)
Vomiting	1 (0.2)	0	1 (0.1)
Fatal	0	0	0
Unknown	2 (0.4)	0	2 (0.3)
Nausea	2 (0.4)	0	2 (0.3)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:27

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Dry mouth			
Number of patients with at least one event	208 (39.3)	2 (1.0)	210 (28.6)
Dry mouth	205 (38.8)	1 (0.5)	206 (28.1)
Aptyalism	2 (0.4)	0	2 (0.3)
Lip dry	2 (0.4)	1 (0.5)	3 (0.4)
Dry throat	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	0	0	0
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
Treatment-related AEs	194 (36.7)	1 (0.5)	195 (26.6)
Dry mouth	190 (35.9)	0	190 (25.9)
Aptyalism	2 (0.4)	0	2 (0.3)
Dry throat	1 (0.2)	0	1 (0.1)
Lip dry	1 (0.2)	1 (0.5)	2 (0.3)
SAEs	0	0	0
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Dry mouth	1 (0.2)	0	1 (0.1)
Dose reduced	3 (0.6)	0	3 (0.4)
Dry mouth	3 (0.6)	0	3 (0.4)
Drug interrupted	0	0	0
Dose not changed/NA/unknown	205 (38.8)	2 (1.0)	207 (28.2)
Dry mouth	202 (38.2)	1 (0.5)	203 (27.7)
Aptyalism	2 (0.4)	0	2 (0.3)
Lip dry	2 (0.4)	1 (0.5)	3 (0.4)
Dry throat	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Dry mouth	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	207 (39.1)	2 (1.0)	209 (28.5)
Dry mouth	204 (38.6)	1 (0.5)	205 (27.9)
Aptyalism	2 (0.4)	0	2 (0.3)
Lip dry	2 (0.4)	1 (0.5)	3 (0.4)
Dry throat	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	71 (13.4)	1 (0.5)	72 (9.8)
Dry mouth	70 (13.2)	1 (0.5)	71 (9.7)
Aptyalism	1 (0.2)	0	1 (0.1)
Recovering/resolving	8 (1.5)	0	8 (1.1)
Dry mouth	8 (1.5)	0	8 (1.1)
Not recovered/not resolved	137 (25.9)	2 (1.0)	139 (18.9)
Dry mouth	135 (25.5)	1 (0.5)	136 (18.5)
Lip dry	2 (0.4)	1 (0.5)	3 (0.4)

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Aptyalism	1 (0.2)	0	1 (0.1)
Dry throat	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	4 (0.8)	0	4 (0.5)
Dry mouth	4 (0.8)	0	4 (0.5)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:28

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aes13.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Hypersensitivity			
Number of patients with at least one event	56 (10.6)	7 (3.4)	63 (8.6)
Rash	15 (2.8)	1 (0.5)	16 (2.2)
Stomatitis	9 (1.7)	0	9 (1.2)
Pruritus	4 (0.8)	0	4 (0.5)
Conjunctivitis	3 (0.6)	0	3 (0.4)
Eczema	3 (0.6)	2 (1.0)	5 (0.7)
Rash maculo-papular	3 (0.6)	0	3 (0.4)
Dermatitis	2 (0.4)	0	2 (0.3)
Generalised oedema	2 (0.4)	1 (0.5)	3 (0.4)
Localised oedema	2 (0.4)	0	2 (0.3)
Scrotal oedema	2 (0.4)	0	2 (0.3)
Sneezing	2 (0.4)	0	2 (0.3)
Swelling face	2 (0.4)	0	2 (0.3)
Acute respiratory failure	1 (0.2)	0	1 (0.1)
Blister	1 (0.2)	1 (0.5)	2 (0.3)
Conjunctival oedema	1 (0.2)	0	1 (0.1)
Dermatitis acneiform	1 (0.2)	0	1 (0.1)
Dermatitis bullous	1 (0.2)	0	1 (0.1)
Erythema	1 (0.2)	0	1 (0.1)
Eye swelling	1 (0.2)	0	1 (0.1)
Flushing	1 (0.2)	0	1 (0.1)
Infusion related reaction	1 (0.2)	0	1 (0.1)
Periorbital oedema	1 (0.2)	0	1 (0.1)
Pneumonitis	1 (0.2)	0	1 (0.1)
Rash erythematous	1 (0.2)	0	1 (0.1)
Respiratory distress	1 (0.2)	0	1 (0.1)
Swelling of eyelid	1 (0.2)	0	1 (0.1)
Swollen tongue	1 (0.2)	0	1 (0.1)
Dermatitis contact	0	1 (0.5)	1 (0.1)
Erythema multiforme	0	1 (0.5)	1 (0.1)
Hypersensitivity	0	1 (0.5)	1 (0.1)
Seasonal allergy	0	1 (0.5)	1 (0.1)
Skin erosion	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	5 (0.9)	0	5 (0.7)
Acute respiratory failure	1 (0.2)	0	1 (0.1)
Generalised oedema	1 (0.2)	0	1 (0.1)
Periorbital oedema	1 (0.2)	0	1 (0.1)
Pneumonitis	1 (0.2)	0	1 (0.1)
Stomatitis	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
Treatment-related AEs			
Stomatitis	20 (3.8)	0	20 (2.7)
Rash	6 (1.1)	0	6 (0.8)
Generalised oedema	3 (0.6)	0	3 (0.4)
Pruritus	2 (0.4)	0	2 (0.3)
Dermatitis acneiform	2 (0.4)	0	2 (0.3)
Erythema	1 (0.2)	0	1 (0.1)
	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Flushing	1 (0.2)	0	1 (0.1)
Localised oedema	1 (0.2)	0	1 (0.1)
Rash maculo-papular	1 (0.2)	0	1 (0.1)
Sneezing	1 (0.2)	0	1 (0.1)
Swelling face	1 (0.2)	0	1 (0.1)
Swollen tongue	1 (0.2)	0	1 (0.1)
SAEs	3 (0.6)	0	3 (0.4)
Acute respiratory failure	1 (0.2)	0	1 (0.1)
Generalised oedema	1 (0.2)	0	1 (0.1)
Stomatitis	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Eye swelling	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	55 (10.4)	7 (3.4)	62 (8.4)
Rash	15 (2.8)	1 (0.5)	16 (2.2)
Stomatitis	9 (1.7)	0	9 (1.2)
Pruritus	4 (0.8)	0	4 (0.5)
Conjunctivitis	3 (0.6)	0	3 (0.4)
Eczema	3 (0.6)	2 (1.0)	5 (0.7)
Rash maculo-papular	3 (0.6)	0	3 (0.4)
Dermatitis	2 (0.4)	0	2 (0.3)
Generalised oedema	2 (0.4)	1 (0.5)	3 (0.4)
Localised oedema	2 (0.4)	0	2 (0.3)
Scrotal oedema	2 (0.4)	0	2 (0.3)
Sneezing	2 (0.4)	0	2 (0.3)
Swelling face	2 (0.4)	0	2 (0.3)
Acute respiratory failure	1 (0.2)	0	1 (0.1)
Blister	1 (0.2)	1 (0.5)	2 (0.3)
Conjunctival oedema	1 (0.2)	0	1 (0.1)
Dermatitis acneiform	1 (0.2)	0	1 (0.1)
Dermatitis bullous	1 (0.2)	0	1 (0.1)
Erythema	1 (0.2)	0	1 (0.1)
Flushing	1 (0.2)	0	1 (0.1)
Infusion related reaction	1 (0.2)	0	1 (0.1)
Periorbital oedema	1 (0.2)	0	1 (0.1)
Pneumonitis	1 (0.2)	0	1 (0.1)
Rash erythematous	1 (0.2)	0	1 (0.1)
Respiratory distress	1 (0.2)	0	1 (0.1)
Swelling of eyelid	1 (0.2)	0	1 (0.1)
Swollen tongue	1 (0.2)	0	1 (0.1)
Dermatitis contact	0	1 (0.5)	1 (0.1)
Erythema multiforme	0	1 (0.5)	1 (0.1)
Hypersensitivity	0	1 (0.5)	1 (0.1)
Seasonal allergy	0	1 (0.5)	1 (0.1)
Skin erosion	0	1 (0.5)	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	1 (0.2)	0	1 (0.1)
Stomatitis	1 (0.2)	0	1 (0.1)
Drug interrupted	0	0	0
Dose not changed/NA/unknown	56 (10.6)	7 (3.4)	63 (8.6)
Rash	15 (2.8)	1 (0.5)	16 (2.2)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Stomatitis	8 (1.5)	0	8 (1.1)
Pruritus	4 (0.8)	0	4 (0.5)
Conjunctivitis	3 (0.6)	0	3 (0.4)
Eczema	3 (0.6)	2 (1.0)	5 (0.7)
Rash maculo-papular	3 (0.6)	0	3 (0.4)
Dermatitis	2 (0.4)	0	2 (0.3)
Generalised oedema	2 (0.4)	1 (0.5)	3 (0.4)
Localised oedema	2 (0.4)	0	2 (0.3)
Scrotal oedema	2 (0.4)	0	2 (0.3)
Sneezing	2 (0.4)	0	2 (0.3)
Swelling face	2 (0.4)	0	2 (0.3)
Acute respiratory failure	1 (0.2)	0	1 (0.1)
Blister	1 (0.2)	1 (0.5)	2 (0.3)
Conjunctival oedema	1 (0.2)	0	1 (0.1)
Dermatitis acneiform	1 (0.2)	0	1 (0.1)
Dermatitis bullous	1 (0.2)	0	1 (0.1)
Erythema	1 (0.2)	0	1 (0.1)
Eye swelling	1 (0.2)	0	1 (0.1)
Flushing	1 (0.2)	0	1 (0.1)
Infusion related reaction	1 (0.2)	0	1 (0.1)
Periorbital oedema	1 (0.2)	0	1 (0.1)
Pneumonitis	1 (0.2)	0	1 (0.1)
Rash erythematous	1 (0.2)	0	1 (0.1)
Respiratory distress	1 (0.2)	0	1 (0.1)
Swelling of eyelid	1 (0.2)	0	1 (0.1)
Swollen tongue	1 (0.2)	0	1 (0.1)
Dermatitis contact	0	1 (0.5)	1 (0.1)
Erythema multiforme	0	1 (0.5)	1 (0.1)
Hypersensitivity	0	1 (0.5)	1 (0.1)
Seasonal allergy	0	1 (0.5)	1 (0.1)
Skin erosion	0	1 (0.5)	1 (0.1)
AE outcome			
Recovered/resolved	38 (7.2)	5 (2.4)	43 (5.9)
Rash	12 (2.3)	1 (0.5)	13 (1.8)
Stomatitis	4 (0.8)	0	4 (0.5)
Conjunctivitis	3 (0.6)	0	3 (0.4)
Dermatitis	2 (0.4)	0	2 (0.3)
Eczema	2 (0.4)	1 (0.5)	3 (0.4)
Pruritus	2 (0.4)	0	2 (0.3)
Rash maculo-papular	2 (0.4)	0	2 (0.3)
Sneezing	2 (0.4)	0	2 (0.3)
Acute respiratory failure	1 (0.2)	0	1 (0.1)
Conjunctival oedema	1 (0.2)	0	1 (0.1)
Dermatitis acneiform	1 (0.2)	0	1 (0.1)
Dermatitis bullous	1 (0.2)	0	1 (0.1)
Infusion related reaction	1 (0.2)	0	1 (0.1)
Localised oedema	1 (0.2)	0	1 (0.1)
Pneumonitis	1 (0.2)	0	1 (0.1)
Rash erythematous	1 (0.2)	0	1 (0.1)
Respiratory distress	1 (0.2)	0	1 (0.1)
Scrotal oedema	1 (0.2)	0	1 (0.1)
Swelling face	1 (0.2)	0	1 (0.1)
Swollen tongue	1 (0.2)	0	1 (0.1)
Blister	0	1 (0.5)	1 (0.1)
Dermatitis contact	0	1 (0.5)	1 (0.1)
Erythema multiforme	0	1 (0.5)	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Hypersensitivity	0	1 (0.5)	1 (0.1)
Seasonal allergy	0	1 (0.5)	1 (0.1)
Skin erosion	0	1 (0.5)	1 (0.1)
Recovering/resolving	2 (0.4)	0	2 (0.3)
Erythema	1 (0.2)	0	1 (0.1)
Rash	1 (0.2)	0	1 (0.1)
Swelling of eyelid	1 (0.2)	0	1 (0.1)
Not recovered/not resolved	20 (3.8)	3 (1.5)	23 (3.1)
Stomatitis	5 (0.9)	0	5 (0.7)
Pruritus	3 (0.6)	0	3 (0.4)
Generalised oedema	2 (0.4)	1 (0.5)	3 (0.4)
Rash	2 (0.4)	0	2 (0.3)
Blister	1 (0.2)	0	1 (0.1)
Eczema	1 (0.2)	2 (1.0)	3 (0.4)
Eye swelling	1 (0.2)	0	1 (0.1)
Localised oedema	1 (0.2)	0	1 (0.1)
Periorbital oedema	1 (0.2)	0	1 (0.1)
Rash maculo-papular	1 (0.2)	0	1 (0.1)
Scrotal oedema	1 (0.2)	0	1 (0.1)
Swelling face	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	1 (0.2)	0	1 (0.1)
Flushing	1 (0.2)	0	1 (0.1)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:28

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-
aes13.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Hepatotoxicity			
Number of patients with at least one event	54 (10.2)	16 (7.8)	70 (9.5)
Aspartate aminotransferase increased	22 (4.2)	5 (2.4)	27 (3.7)
Blood alkaline phosphatase increased	20 (3.8)	2 (1.0)	22 (3.0)
Hypoalbuminaemia	20 (3.8)	3 (1.5)	23 (3.1)
Alanine aminotransferase increased	15 (2.8)	6 (2.9)	21 (2.9)
Hyperbilirubinaemia	7 (1.3)	3 (1.5)	10 (1.4)
Ascites	6 (1.1)	0	6 (0.8)
Gamma-glutamyltransferase increased	5 (0.9)	0	5 (0.7)
Acute hepatic failure	1 (0.2)	0	1 (0.1)
Cholestasis	1 (0.2)	1 (0.5)	2 (0.3)
Hepatic cytolysis	1 (0.2)	2 (1.0)	3 (0.4)
Hepatic encephalopathy	1 (0.2)	0	1 (0.1)
Hepatic failure	1 (0.2)	0	1 (0.1)
Hepatic lesion	1 (0.2)	0	1 (0.1)
Hepatitis	1 (0.2)	0	1 (0.1)
International normalised ratio increased	1 (0.2)	1 (0.5)	2 (0.3)
Jaundice	1 (0.2)	1 (0.5)	2 (0.3)
Transaminases increased	0	2 (1.0)	2 (0.3)
Maximum grade			
Grade 3 AEs	11 (2.1)	5 (2.4)	16 (2.2)
Blood alkaline phosphatase increased	6 (1.1)	0	6 (0.8)
Alanine aminotransferase increased	2 (0.4)	2 (1.0)	4 (0.5)
Aspartate aminotransferase increased	2 (0.4)	1 (0.5)	3 (0.4)
Gamma-glutamyltransferase increased	2 (0.4)	0	2 (0.3)
Hyperbilirubinaemia	2 (0.4)	1 (0.5)	3 (0.4)
Ascites	1 (0.2)	0	1 (0.1)
Cholestasis	1 (0.2)	1 (0.5)	2 (0.3)
Hepatic lesion	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	0	1 (0.5)	1 (0.1)
Grade 4 AEs	2 (0.4)	0	2 (0.3)
Aspartate aminotransferase increased	1 (0.2)	0	1 (0.1)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Grade 5 AEs	2 (0.4)	0	2 (0.3)
Acute hepatic failure	1 (0.2)	0	1 (0.1)
Hepatic failure	1 (0.2)	0	1 (0.1)
Treatment-related AEs			
Aspartate aminotransferase increased	21 (4.0)	6 (2.9)	27 (3.7)
Alanine aminotransferase increased	8 (1.5)	3 (1.5)	11 (1.5)
Blood alkaline phosphatase increased	7 (1.3)	4 (2.0)	11 (1.5)
Hypoalbuminaemia	7 (1.3)	1 (0.5)	8 (1.1)
Gamma-glutamyltransferase increased	4 (0.8)	0	4 (0.5)
Ascites	2 (0.4)	0	2 (0.3)
Hepatic cytolysis	1 (0.2)	1 (0.5)	2 (0.3)
Hyperbilirubinaemia	1 (0.2)	1 (0.5)	2 (0.3)
Transaminases increased	0	1 (0.5)	1 (0.1)
SAEs			
Acute hepatic failure	5 (0.9)	2 (1.0)	7 (1.0)
Ascites	1 (0.2)	0	1 (0.1)
	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Cholestasis	1 (0.2)	0	1 (0.1)
Hepatic failure	1 (0.2)	0	1 (0.1)
Hepatic lesion	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	0	2 (1.0)	2 (0.3)
Action taken with PSMA-617			
Drug withdrawn	3 (0.6)	1 (0.5)	4 (0.5)
Acute hepatic failure	1 (0.2)	0	1 (0.1)
Ascites	1 (0.2)	0	1 (0.1)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Hypoalbuminaemia	0	1 (0.5)	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	4 (0.8)	1 (0.5)	5 (0.7)
Aspartate aminotransferase increased	3 (0.6)	0	3 (0.4)
Alanine aminotransferase increased	1 (0.2)	0	1 (0.1)
Cholestasis	1 (0.2)	0	1 (0.1)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Hypoalbuminaemia	0	1 (0.5)	1 (0.1)
Dose not changed/NA/unknown	53 (10.0)	16 (7.8)	69 (9.4)
Aspartate aminotransferase increased	21 (4.0)	5 (2.4)	26 (3.5)
Blood alkaline phosphatase increased	20 (3.8)	2 (1.0)	22 (3.0)
Hypoalbuminaemia	20 (3.8)	3 (1.5)	23 (3.1)
Alanine aminotransferase increased	14 (2.6)	6 (2.9)	20 (2.7)
Hyperbilirubinaemia	7 (1.3)	3 (1.5)	10 (1.4)
Ascites	5 (0.9)	0	5 (0.7)
Gamma-glutamyltransferase increased	4 (0.8)	0	4 (0.5)
Hepatic cytolysis	1 (0.2)	2 (1.0)	3 (0.4)
Hepatic encephalopathy	1 (0.2)	0	1 (0.1)
Hepatic failure	1 (0.2)	0	1 (0.1)
Hepatic lesion	1 (0.2)	0	1 (0.1)
Hepatitis	1 (0.2)	0	1 (0.1)
International normalised ratio increased	1 (0.2)	1 (0.5)	2 (0.3)
Jaundice	1 (0.2)	1 (0.5)	2 (0.3)
Cholestasis	0	1 (0.5)	1 (0.1)
Transaminases increased	0	2 (1.0)	2 (0.3)
Action taken with BSC/BSoC			
Drug withdrawn	5 (0.9)	1 (0.5)	6 (0.8)
Alanine aminotransferase increased	1 (0.2)	0	1 (0.1)
Ascites	1 (0.2)	0	1 (0.1)
Aspartate aminotransferase increased	1 (0.2)	0	1 (0.1)
Blood alkaline phosphatase increased	1 (0.2)	0	1 (0.1)
Cholestasis	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	1 (0.2)	1 (0.5)	2 (0.3)
Dose reduced	0	2 (1.0)	2 (0.3)
Alanine aminotransferase increased	0	1 (0.5)	1 (0.1)
Aspartate aminotransferase increased	0	1 (0.5)	1 (0.1)
Transaminases increased	0	1 (0.5)	1 (0.1)
Drug interrupted	5 (0.9)	3 (1.5)	8 (1.1)
Aspartate aminotransferase increased	2 (0.4)	1 (0.5)	3 (0.4)
Hyperbilirubinaemia	2 (0.4)	0	2 (0.3)
Alanine aminotransferase increased	1 (0.2)	1 (0.5)	2 (0.3)
Hepatic failure	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	0	1 (0.5)	1 (0.1)
Transaminases increased	0	1 (0.5)	1 (0.1)
Dose not changed/NA/unknown	50 (9.5)	11 (5.4)	61 (8.3)
Aspartate aminotransferase increased	21 (4.0)	3 (1.5)	24 (3.3)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Hypoalbuminaemia	20 (3.8)	3 (1.5)	23 (3.1)
Blood alkaline phosphatase increased	19 (3.6)	2 (1.0)	21 (2.9)
Alanine aminotransferase increased	13 (2.5)	4 (2.0)	17 (2.3)
Hyperbilirubinaemia	6 (1.1)	3 (1.5)	9 (1.2)
Ascites	5 (0.9)	0	5 (0.7)
Gamma-glutamyltransferase increased	5 (0.9)	0	5 (0.7)
Acute hepatic failure	1 (0.2)	0	1 (0.1)
Hepatic encephalopathy	1 (0.2)	0	1 (0.1)
Hepatic lesion	1 (0.2)	0	1 (0.1)
Hepatitis	1 (0.2)	0	1 (0.1)
International normalised ratio increased	1 (0.2)	1 (0.5)	2 (0.3)
Jaundice	1 (0.2)	1 (0.5)	2 (0.3)
Cholestasis	0	1 (0.5)	1 (0.1)
Transaminases increased	0	1 (0.5)	1 (0.1)
AE outcome			
Recovered/resolved	31 (5.9)	7 (3.4)	38 (5.2)
Aspartate aminotransferase increased	15 (2.8)	3 (1.5)	18 (2.5)
Alanine aminotransferase increased	11 (2.1)	4 (2.0)	15 (2.0)
Hypoalbuminaemia	10 (1.9)	2 (1.0)	12 (1.6)
Blood alkaline phosphatase increased	6 (1.1)	0	6 (0.8)
Hyperbilirubinaemia	3 (0.6)	0	3 (0.4)
Ascites	2 (0.4)	0	2 (0.3)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	1 (0.2)	0	1 (0.1)
Hepatic lesion	1 (0.2)	0	1 (0.1)
Jaundice	1 (0.2)	0	1 (0.1)
Transaminases increased	0	1 (0.5)	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	30 (5.7)	10 (4.9)	40 (5.4)
Blood alkaline phosphatase increased	14 (2.6)	2 (1.0)	16 (2.2)
Hypoalbuminaemia	10 (1.9)	1 (0.5)	11 (1.5)
Aspartate aminotransferase increased	9 (1.7)	2 (1.0)	11 (1.5)
Alanine aminotransferase increased	6 (1.1)	2 (1.0)	8 (1.1)
Gamma-glutamyltransferase increased	4 (0.8)	0	4 (0.5)
Hyperbilirubinaemia	4 (0.8)	3 (1.5)	7 (1.0)
Ascites	3 (0.6)	0	3 (0.4)
Hepatic encephalopathy	1 (0.2)	0	1 (0.1)
Hepatitis	1 (0.2)	0	1 (0.1)
International normalised ratio increased	1 (0.2)	1 (0.5)	2 (0.3)
Cholestasis	0	1 (0.5)	1 (0.1)
Hepatic cytolysis	0	2 (1.0)	2 (0.3)
Jaundice	0	1 (0.5)	1 (0.1)
Transaminases increased	0	1 (0.5)	1 (0.1)
Recovered/resolved with sequelae	2 (0.4)	0	2 (0.3)
Ascites	1 (0.2)	0	1 (0.1)
Cholestasis	1 (0.2)	0	1 (0.1)
Fatal	2 (0.4)	0	2 (0.3)
Acute hepatic failure	1 (0.2)	0	1 (0.1)
Hepatic failure	1 (0.2)	0	1 (0.1)
Unknown	1 (0.2)	0	1 (0.1)
Blood alkaline phosphatase increased	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
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Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:29

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aes3.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Renal toxicity			
Number of patients with at least one event	46 (8.7)	12 (5.9)	58 (7.9)
Blood creatinine increased	28 (5.3)	5 (2.4)	33 (4.5)
Acute kidney injury	19 (3.6)	8 (3.9)	27 (3.7)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Renal failure	1 (0.2)	0	1 (0.1)
Urine output decreased	1 (0.2)	1 (0.5)	2 (0.3)
Maximum grade			
Grade 3 AEs	18 (3.4)	6 (2.9)	24 (3.3)
Acute kidney injury	16 (3.0)	5 (2.4)	21 (2.9)
Blood creatinine increased	1 (0.2)	1 (0.5)	2 (0.3)
Urine output decreased	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
Treatment-related AEs	18 (3.4)	0	18 (2.5)
Blood creatinine increased	14 (2.6)	0	14 (1.9)
Acute kidney injury	4 (0.8)	0	4 (0.5)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
SAEs			
Acute kidney injury	9 (1.7)	7 (3.4)	16 (2.2)
Blood creatinine increased	9 (1.7)	6 (2.9)	15 (2.0)
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Blood creatinine increased	1 (0.2)	0	1 (0.1)
Dose reduced	2 (0.4)	0	2 (0.3)
Blood creatinine increased	2 (0.4)	0	2 (0.3)
Drug interrupted	2 (0.4)	0	2 (0.3)
Acute kidney injury	1 (0.2)	0	1 (0.1)
Blood creatinine increased	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	42 (7.9)	12 (5.9)	54 (7.4)
Blood creatinine increased	25 (4.7)	5 (2.4)	30 (4.1)
Acute kidney injury	18 (3.4)	8 (3.9)	26 (3.5)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Renal failure	1 (0.2)	0	1 (0.1)
Urine output decreased	1 (0.2)	1 (0.5)	2 (0.3)
Action taken with BSC/BSoC			
Drug withdrawn	0	1 (0.5)	1 (0.1)
Blood creatinine increased	0	1 (0.5)	1 (0.1)
Dose reduced	1 (0.2)	0	1 (0.1)
Blood creatinine increased	1 (0.2)	0	1 (0.1)
Drug interrupted	1 (0.2)	2 (1.0)	3 (0.4)
Acute kidney injury	1 (0.2)	1 (0.5)	2 (0.3)
Blood creatinine increased	0	1 (0.5)	1 (0.1)
Dose not changed/NA/unknown	44 (8.3)	10 (4.9)	54 (7.4)

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177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Blood creatinine increased	27 (5.1)	4 (2.0)	31 (4.2)
Acute kidney injury	18 (3.4)	7 (3.4)	25 (3.4)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Renal failure	1 (0.2)	0	1 (0.1)
Urine output decreased	1 (0.2)	1 (0.5)	2 (0.3)
AE outcome			
Recovered/resolved	29 (5.5)	8 (3.9)	37 (5.0)
Blood creatinine increased	16 (3.0)	3 (1.5)	19 (2.6)
Acute kidney injury	11 (2.1)	5 (2.4)	16 (2.2)
Blood urea increased	1 (0.2)	0	1 (0.1)
Renal failure	1 (0.2)	0	1 (0.1)
Urine output decreased	1 (0.2)	0	1 (0.1)
Recovering/resolving	1 (0.2)	1 (0.5)	2 (0.3)
Acute kidney injury	1 (0.2)	1 (0.5)	2 (0.3)
Not recovered/not resolved	18 (3.4)	3 (1.5)	21 (2.9)
Blood creatinine increased	13 (2.5)	2 (1.0)	15 (2.0)
Acute kidney injury	6 (1.1)	1 (0.5)	7 (1.0)
Proteinuria	1 (0.2)	0	1 (0.1)
Urine output decreased	0	1 (0.5)	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	1 (0.2)	1 (0.5)	2 (0.3)
Acute kidney injury	1 (0.2)	1 (0.5)	2 (0.3)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:30

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Late renal toxicity			
Number of patients with at least one event	25 (4.7)	2 (1.0)	27 (3.7)
Acute kidney injury	12 (2.3)	2 (1.0)	14 (1.9)
Blood creatinine increased	11 (2.1)	0	11 (1.5)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Urine output decreased	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	12 (2.3)	1 (0.5)	13 (1.8)
Acute kidney injury	10 (1.9)	1 (0.5)	11 (1.5)
Blood creatinine increased	1 (0.2)	0	1 (0.1)
Urine output decreased	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
Treatment-related AEs	10 (1.9)	0	10 (1.4)
Blood creatinine increased	7 (1.3)	0	7 (1.0)
Acute kidney injury	2 (0.4)	0	2 (0.3)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
SAEs	7 (1.3)	1 (0.5)	8 (1.1)
Acute kidney injury	7 (1.3)	1 (0.5)	8 (1.1)
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Blood creatinine increased	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	1 (0.2)	0	1 (0.1)
Blood creatinine increased	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	23 (4.3)	2 (1.0)	25 (3.4)
Acute kidney injury	12 (2.3)	2 (1.0)	14 (1.9)
Blood creatinine increased	9 (1.7)	0	9 (1.2)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Urine output decreased	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	25 (4.7)	2 (1.0)	27 (3.7)
Acute kidney injury	12 (2.3)	2 (1.0)	14 (1.9)
Blood creatinine increased	11 (2.1)	0	11 (1.5)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Urine output decreased	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	16 (3.0)	1 (0.5)	17 (2.3)
Acute kidney injury	8 (1.5)	1 (0.5)	9 (1.2)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Blood creatinine increased	6 (1.1)	0	6 (0.8)
Blood urea increased	1 (0.2)	0	1 (0.1)
Urine output decreased	1 (0.2)	0	1 (0.1)
Recovering/resolving	1 (0.2)	0	1 (0.1)
Acute kidney injury	1 (0.2)	0	1 (0.1)
Not recovered/not resolved	9 (1.7)	1 (0.5)	10 (1.4)
Blood creatinine increased	6 (1.1)	0	6 (0.8)
Acute kidney injury	3 (0.6)	1 (0.5)	4 (0.5)
Proteinuria	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	0	0	0

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:31

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-aesi3.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Second primary malignancies			
Number of patients with at least one event	12 (2.3)	2 (1.0)	14 (1.9)
Squamous cell carcinoma	4 (0.8)	0	4 (0.5)
Metastases to central nervous system	2 (0.4)	0	2 (0.3)
Metastases to meninges	2 (0.4)	0	2 (0.3)
Basal cell carcinoma	1 (0.2)	1 (0.5)	2 (0.3)
Malignant melanoma	1 (0.2)	0	1 (0.1)
Pancreatic carcinoma	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma of skin	1 (0.2)	0	1 (0.1)
Extradural neoplasm	0	1 (0.5)	1 (0.1)
Squamous cell carcinoma of the tongue	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	3 (0.6)	1 (0.5)	4 (0.5)
Metastases to central nervous system	1 (0.2)	0	1 (0.1)
Metastases to meninges	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma of the tongue	0	1 (0.5)	1 (0.1)
Grade 4 AEs	1 (0.2)	0	1 (0.1)
Pancreatic carcinoma	1 (0.2)	0	1 (0.1)
Grade 5 AEs	1 (0.2)	0	1 (0.1)
Metastases to central nervous system	1 (0.2)	0	1 (0.1)
Treatment-related AEs			
Squamous cell carcinoma	1 (0.2)	0	1 (0.1)
SAEs			
Metastases to central nervous system	4 (0.8)	0	4 (0.5)
Metastases to meninges	2 (0.4)	0	2 (0.3)
Pancreatic carcinoma	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Metastases to central nervous system	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	11 (2.1)	2 (1.0)	13 (1.8)
Squamous cell carcinoma	4 (0.8)	0	4 (0.5)
Metastases to meninges	2 (0.4)	0	2 (0.3)
Basal cell carcinoma	1 (0.2)	1 (0.5)	2 (0.3)
Malignant melanoma	1 (0.2)	0	1 (0.1)
Metastases to central nervous system	1 (0.2)	0	1 (0.1)
Pancreatic carcinoma	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma of skin	1 (0.2)	0	1 (0.1)
Extradural neoplasm	0	1 (0.5)	1 (0.1)
Squamous cell carcinoma of the tongue	0	1 (0.5)	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	12 (2.3)	2 (1.0)	14 (1.9)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Squamous cell carcinoma	4 (0.8)	0	4 (0.5)
Metastases to central nervous system	2 (0.4)	0	2 (0.3)
Metastases to meninges	2 (0.4)	0	2 (0.3)
Basal cell carcinoma	1 (0.2)	1 (0.5)	2 (0.3)
Malignant melanoma	1 (0.2)	0	1 (0.1)
Pancreatic carcinoma	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma of skin	1 (0.2)	0	1 (0.1)
Extradural neoplasm	0	1 (0.5)	1 (0.1)
Squamous cell carcinoma of the tongue	0	1 (0.5)	1 (0.1)
AE outcome			
Recovered/resolved	4 (0.8)	2 (1.0)	6 (0.8)
Squamous cell carcinoma	2 (0.4)	0	2 (0.3)
Metastases to meninges	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma of skin	1 (0.2)	0	1 (0.1)
Basal cell carcinoma	0	1 (0.5)	1 (0.1)
Extradural neoplasm	0	1 (0.5)	1 (0.1)
Squamous cell carcinoma of the tongue	0	1 (0.5)	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	5 (0.9)	0	5 (0.7)
Basal cell carcinoma	1 (0.2)	0	1 (0.1)
Malignant melanoma	1 (0.2)	0	1 (0.1)
Metastases to central nervous system	1 (0.2)	0	1 (0.1)
Metastases to meninges	1 (0.2)	0	1 (0.1)
Pancreatic carcinoma	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma	1 (0.2)	0	1 (0.1)
Fatal	1 (0.2)	0	1 (0.1)
Metastases to central nervous system	1 (0.2)	0	1 (0.1)
Unknown	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma	1 (0.2)	0	1 (0.1)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:31

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level
(FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
QT prolongation			
Number of patients with at least one event	9 (1.7)	1 (0.5)	10 (1.4)
Syncope	7 (1.3)	0	7 (1.0)
Ventricular tachycardia	2 (0.4)	0	2 (0.3)
Loss of consciousness	1 (0.2)	0	1 (0.1)
Cardio-respiratory arrest	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	7 (1.3)	0	7 (1.0)
Syncope	6 (1.1)	0	6 (0.8)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	1 (0.5)	1 (0.1)
Cardio-respiratory arrest	0	1 (0.5)	1 (0.1)
Treatment-related AEs	2 (0.4)	0	2 (0.3)
Syncope	1 (0.2)	0	1 (0.1)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
SAEs	6 (1.1)	1 (0.5)	7 (1.0)
Syncope	4 (0.8)	0	4 (0.5)
Ventricular tachycardia	2 (0.4)	0	2 (0.3)
Loss of consciousness	1 (0.2)	0	1 (0.1)
Cardio-respiratory arrest	0	1 (0.5)	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	9 (1.7)	1 (0.5)	10 (1.4)
Syncope	7 (1.3)	0	7 (1.0)
Ventricular tachycardia	2 (0.4)	0	2 (0.3)
Loss of consciousness	1 (0.2)	0	1 (0.1)
Cardio-respiratory arrest	0	1 (0.5)	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	8 (1.5)	1 (0.5)	9 (1.2)
Syncope	7 (1.3)	0	7 (1.0)
Loss of consciousness	1 (0.2)	0	1 (0.1)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
Cardio-respiratory arrest	0	1 (0.5)	1 (0.1)
AE outcome			
Recovered/resolved	9 (1.7)	0	9 (1.2)
Syncope	7 (1.3)	0	7 (1.0)
Ventricular tachycardia	2 (0.4)	0	2 (0.3)
Loss of consciousness	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Not recovered/not resolved	0	0	0
Recovered/resolved with sequelae	0	0	0
Fatal	0	1 (0.5)	1 (0.1)
Cardio-respiratory arrest	0	1 (0.5)	1 (0.1)
Unknown	0	0	0

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:32

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Intracranial haemorrhage			
Number of patients with at least one event	7 (1.3)	3 (1.5)	10 (1.4)
Subdural haematoma	4 (0.8)	2 (1.0)	6 (0.8)
Haemorrhage intracranial	2 (0.4)	0	2 (0.3)
Cerebral haemorrhage	1 (0.2)	0	1 (0.1)
Cerebral haematoma	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	3 (0.6)	1 (0.5)	4 (0.5)
Subdural haematoma	3 (0.6)	1 (0.5)	4 (0.5)
Grade 4 AEs	0	0	0
Grade 5 AEs	2 (0.4)	1 (0.5)	3 (0.4)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)
Subdural haematoma	1 (0.2)	1 (0.5)	2 (0.3)
Treatment-related AEs	3 (0.6)	0	3 (0.4)
Haemorrhage intracranial	2 (0.4)	0	2 (0.3)
Subdural haematoma	1 (0.2)	0	1 (0.1)
SAEs			
Subdural haematoma	7 (1.3)	2 (1.0)	9 (1.2)
Haemorrhage intracranial	4 (0.8)	2 (1.0)	6 (0.8)
Cerebral haemorrhage	2 (0.4)	0	2 (0.3)
Cerebral haematoma	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Subdural haematoma	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	6 (1.1)	3 (1.5)	9 (1.2)
Subdural haematoma	3 (0.6)	2 (1.0)	5 (0.7)
Haemorrhage intracranial	2 (0.4)	0	2 (0.3)
Cerebral haemorrhage	1 (0.2)	0	1 (0.1)
Cerebral haematoma	0	1 (0.5)	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	2 (0.4)	0	2 (0.3)
Cerebral haemorrhage	1 (0.2)	0	1 (0.1)
Subdural haematoma	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	5 (0.9)	3 (1.5)	8 (1.1)
Subdural haematoma	3 (0.6)	2 (1.0)	5 (0.7)
Haemorrhage intracranial	2 (0.4)	0	2 (0.3)
Cerebral haematoma	0	1 (0.5)	1 (0.1)
AE outcome			
Recovered/resolved	2 (0.4)	1 (0.5)	3 (0.4)
Subdural haematoma	2 (0.4)	1 (0.5)	3 (0.4)
Recovering/resolving	0	0	0
Not recovered/not resolved	3 (0.6)	1 (0.5)	4 (0.5)
Cerebral haemorrhage	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)
Subdural haematoma	1 (0.2)	0	1 (0.1)
Cerebral haematoma	0	1 (0.5)	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	2 (0.4)	1 (0.5)	3 (0.4)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)
Subdural haematoma	1 (0.2)	1 (0.5)	2 (0.3)
Unknown	0	0	0

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:33

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Medication errors			
Number of patients with at least one event	1 (0.2)	0	1 (0.1)
Overdose	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	0	0	0
Grade 4 AEs	1 (0.2)	0	1 (0.1)
Overdose	1 (0.2)	0	1 (0.1)
Grade 5 AEs	0	0	0
Treatment-related AEs	0	0	0
SAEs	1 (0.2)	0	1 (0.1)
Overdose	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)
Overdose	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)
Overdose	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	1 (0.2)	0	1 (0.1)
Overdose	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	0	0	0
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	0	0	0

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:33

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Radiotoxicity including inadvertent exposure			
Number of patients with at least one event	1 (0.2)	1 (0.5)	2 (0.3)
Cystitis radiation	1 (0.2)	0	1 (0.1)
Radiation skin injury	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	1 (0.2)	0	1 (0.1)
Cystitis radiation	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
Treatment-related AEs	0	0	0
SAEs	0	0	0
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	1 (0.2)	1 (0.5)	2 (0.3)
Cystitis radiation	1 (0.2)	0	1 (0.1)
Radiation skin injury	0	1 (0.5)	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	1 (0.2)	1 (0.5)	2 (0.3)
Cystitis radiation	1 (0.2)	0	1 (0.1)
Radiation skin injury	0	1 (0.5)	1 (0.1)
AE outcome			
Recovered/resolved	1 (0.2)	1 (0.5)	2 (0.3)
Cystitis radiation	1 (0.2)	0	1 (0.1)
Radiation skin injury	0	1 (0.5)	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	0	0	0
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	0	0	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
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Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:34

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aes3.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
 177Lu-PSMA-617 SCS update
 Table 2-1-5-3 Incidence of randomized treatment-emergent safety topics of interest including preferred term level (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Reproductive toxicity			
Number of patients with at least one event	1 (0.2)	0	1 (0.1)
Vascular malformation	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	1 (0.2)	0	1 (0.1)
Vascular malformation	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
Treatment-related AEs	0	0	0
SAEs	1 (0.2)	0	1 (0.1)
Vascular malformation	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)
Vascular malformation	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	1 (0.2)	0	1 (0.1)
Vascular malformation	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)
Vascular malformation	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	1 (0.2)	0	1 (0.1)
Vascular malformation	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	0	0	0
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	0	0	0

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment. Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3 2021-09-23 10:35

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

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Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3s Incidence of study treatment-emergent safety topics of interest including preferred term level (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Myelosuppression	
Number of patients with at least one event	11 (36.7)
Anaemia	9 (30.0)
Lymphopenia	5 (16.7)
Thrombocytopenia	4 (13.3)
Leukopenia	3 (10.0)
Maximum grade	
Grade 3 AEs	4 (13.3)
Anaemia	2 (6.7)
Leukopenia	1 (3.3)
Thrombocytopenia	1 (3.3)
Grade 4 AEs	2 (6.7)
Lymphopenia	1 (3.3)
Thrombocytopenia	1 (3.3)
Grade 5 AEs	0
Treatment-related AEs	9 (30.0)
Anaemia	7 (23.3)
Lymphopenia	4 (13.3)
Thrombocytopenia	3 (10.0)
Leukopenia	2 (6.7)
SAEs	3 (10.0)
Anaemia	2 (6.7)
Thrombocytopenia	2 (6.7)
Action taken with PSMA-617	
Drug withdrawn	2 (6.7)
Anaemia	1 (3.3)
Thrombocytopenia	1 (3.3)
Dose reduced	2 (6.7)
Leukopenia	2 (6.7)
Drug interrupted	2 (6.7)
Anaemia	1 (3.3)
Thrombocytopenia	1 (3.3)
Dose not changed/NA/unknown	10 (33.3)
Anaemia	8 (26.7)
Lymphopenia	5 (16.7)
Thrombocytopenia	4 (13.3)
Leukopenia	3 (10.0)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	11 (36.7)
Anaemia	9 (30.0)
Lymphopenia	5 (16.7)
Thrombocytopenia	4 (13.3)
Leukopenia	3 (10.0)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
AE outcome	
Recovered/resolved	3 (10.0)
Anaemia	2 (6.7)
Leukopenia	1 (3.3)
Recovering/resolving	0
Not recovered/not resolved	9 (30.0)
Anaemia	7 (23.3)
Lymphopenia	5 (16.7)
Leukopenia	3 (10.0)
Thrombocytopenia	3 (10.0)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	1 (3.3)
Anaemia	1 (3.3)
Thrombocytopenia	1 (3.3)

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3s 2021-09-23 11:08

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177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3s Incidence of study treatment-emergent safety topics of interest including preferred term level (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Nausea and Vomiting	
Number of patients with at least one event	11 (36.7)
Nausea	11 (36.7)
Vomiting	4 (13.3)
Maximum grade	0
Grade 3 AEs	0
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	7 (23.3)
Nausea	7 (23.3)
Vomiting	3 (10.0)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	11 (36.7)
Nausea	11 (36.7)
Vomiting	4 (13.3)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	11 (36.7)
Nausea	11 (36.7)
Vomiting	4 (13.3)
AE outcome	
Recovered/resolved	8 (26.7)
Nausea	7 (23.3)
Vomiting	4 (13.3)
Recovering/resolving	0
Not recovered/not resolved	4 (13.3)
Nausea	4 (13.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)
n (%)

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Numbers (n) represent counts of patients.

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177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3s Incidence of study treatment-emergent safety topics of interest including preferred term level (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Fatigue	
Number of patients with at least one event	6 (20.0)
Fatigue	5 (16.7)
Asthenia	1 (3.3)
Maximum grade	
Grade 3 AEs	2 (6.7)
Asthenia	1 (3.3)
Fatigue	1 (3.3)
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	4 (13.3)
Fatigue	3 (10.0)
Asthenia	1 (3.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	6 (20.0)
Fatigue	5 (16.7)
Asthenia	1 (3.3)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	6 (20.0)
Fatigue	5 (16.7)
Asthenia	1 (3.3)
AE outcome	
Recovered/resolved	0
Recovering/resolving	1 (3.3)
Fatigue	1 (3.3)
Not recovered/not resolved	5 (16.7)
Fatigue	4 (13.3)
Asthenia	1 (3.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)
n (%)

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3s 2021-09-23 11:09

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177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3s Incidence of study treatment-emergent safety topics of interest including preferred term level (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Dry mouth	
Number of patients with at least one event	5 (16.7)
Dry mouth	5 (16.7)
Maximum grade	
Grade 3 AEs	0
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	4 (13.3)
Dry mouth	4 (13.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	5 (16.7)
Dry mouth	5 (16.7)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	5 (16.7)
Dry mouth	5 (16.7)
AE outcome	
Recovered/resolved	1 (3.3)
Dry mouth	1 (3.3)
Recovering/resolving	0
Not recovered/not resolved	4 (13.3)
Dry mouth	4 (13.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)
n (%)

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3s 2021-09-23 11:10

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177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3s Incidence of study treatment-emergent safety topics of interest including preferred term level (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Renal toxicity	
Number of patients with at least one event	5 (16.7)
Blood creatinine increased	3 (10.0)
Glomerular filtration rate decreased	1 (3.3)
Renal impairment	1 (3.3)
Maximum grade	
Grade 3 AEs	0
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	4 (13.3)
Blood creatinine increased	3 (10.0)
Glomerular filtration rate decreased	1 (3.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	5 (16.7)
Blood creatinine increased	3 (10.0)
Glomerular filtration rate decreased	1 (3.3)
Renal impairment	1 (3.3)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	5 (16.7)
Blood creatinine increased	3 (10.0)
Glomerular filtration rate decreased	1 (3.3)
Renal impairment	1 (3.3)
AE outcome	
Recovered/resolved	1 (3.3)
Blood creatinine increased	1 (3.3)
Recovering/resolving	0
Not recovered/not resolved	4 (13.3)
Blood creatinine increased	2 (6.7)
Glomerular filtration rate decreased	1 (3.3)
Renal impairment	1 (3.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)
n (%)

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3s 2021-09-23 11:10

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177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3s Incidence of study treatment-emergent safety topics of interest including preferred term level (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Hypersensitivity	
Number of patients with at least one event	3 (10.0)
Pruritus	2 (6.7)
Generalised oedema	1 (3.3)
Rash	1 (3.3)
Throat tightness	1 (3.3)
Maximum grade	
Grade 3 AEs	1 (3.3)
Generalised oedema	1 (3.3)
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	1 (3.3)
Pruritus	1 (3.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	1 (3.3)
Generalised oedema	1 (3.3)
Dose not changed/NA/unknown	3 (10.0)
Pruritus	2 (6.7)
Rash	1 (3.3)
Throat tightness	1 (3.3)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	1 (3.3)
Generalised oedema	1 (3.3)
Dose not changed/NA/unknown	3 (10.0)
Pruritus	2 (6.7)
Rash	1 (3.3)
Throat tightness	1 (3.3)
AE outcome	
Recovered/resolved	2 (6.7)
Pruritus	2 (6.7)
Recovering/resolving	0
Not recovered/not resolved	2 (6.7)
Generalised oedema	1 (3.3)
Rash	1 (3.3)
Throat tightness	1 (3.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)
n (%)

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3s 2021-09-23 11:11

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177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3s Incidence of study treatment-emergent safety topics of interest including preferred term level (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Hepatotoxicity	
Number of patients with at least one event	2 (6.7)
Blood alkaline phosphatase increased	2 (6.7)
Alanine aminotransferase increased	1 (3.3)
Maximum grade	
Grade 3 AEs	0
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	1 (3.3)
Blood alkaline phosphatase increased	1 (3.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	2 (6.7)
Blood alkaline phosphatase increased	2 (6.7)
Alanine aminotransferase increased	1 (3.3)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	2 (6.7)
Blood alkaline phosphatase increased	2 (6.7)
Alanine aminotransferase increased	1 (3.3)
AE outcome	
Recovered/resolved	2 (6.7)
Alanine aminotransferase increased	1 (3.3)
Blood alkaline phosphatase increased	1 (3.3)
Recovering/resolving	0
Not recovered/not resolved	1 (3.3)
Blood alkaline phosphatase increased	1 (3.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	1 (3.3)
Blood alkaline phosphatase increased	1 (3.3)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)
n (%)

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3s 2021-09-23 11:11

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177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-3s Incidence of study treatment-emergent safety topics of interest including preferred term level (Sub-study safety analysis set)

	Lu-PSMA-617 +BSC/BSoC (N=30) n (%)
Late renal toxicity	
Number of patients with at least one event	2 (6.7)
Blood creatinine increased	1 (3.3)
Glomerular filtration rate decreased	1 (3.3)
Maximum grade	
Grade 3 AEs	0
Grade 4 AEs	0
Grade 5 AEs	0
Treatment-related AEs	2 (6.7)
Blood creatinine increased	1 (3.3)
Glomerular filtration rate decreased	1 (3.3)
SAEs	0
Action taken with PSMA-617	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	2 (6.7)
Blood creatinine increased	1 (3.3)
Glomerular filtration rate decreased	1 (3.3)
Action taken with BSC/BSoC	
Drug withdrawn	0
Dose reduced	0
Drug interrupted	0
Dose not changed/NA/unknown	2 (6.7)
Blood creatinine increased	1 (3.3)
Glomerular filtration rate decreased	1 (3.3)
AE outcome	
Recovered/resolved	0
Recovering/resolving	0
Not recovered/not resolved	2 (6.7)
Blood creatinine increased	1 (3.3)
Glomerular filtration rate decreased	1 (3.3)
Recovered/resolved with sequelae	0
Fatal	0
Unknown	0

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Lu-PSMA-617
+BSC/BSoC
(N=30)
n (%)

Study treatment-emergent safety topics = any safety topic that occurred on or after start of study treatment up to 30 days after last administration of study treatment or prior to the initiation of subsequent anticancer treatment. A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-3s 2021-09-23 11:12

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177Lu-PSMA-617 SCS update

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Table 2-1-5-4 Time to first occurrence of safety topic of interest (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoc (N=529)	BSC/BSoc only (N=205)
Fatigue		
Number of subjects with at least one event, n (%)	260 (49.1)	60 (29.3)
Time to first occurrence (weeks) ^a		
Median (Min-Max)	4.9 (0.1-80.0)	4.6 (0.1-27.9)
Q1-Q3	0.4-12.9	1.3-7.6
Time to first occurrence (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	269 (50.9)	145 (70.7)
Median [95% CI]	33.1 [23.9, NE]	NE [27.9, NE]
Q1-Q3	5.0-NE	8.9-NE
% Event probability estimate [95% CI]		
Week 12	35.3 [31.4, 39.6]	29.2 [22.9, 36.7]
Week 24	46.3 [42.1, 50.8]	39.6 [31.0, 49.6]
Myelosuppression		
Number of subjects with at least one event, n (%)	251 (47.4)	36 (17.6)
Time to first occurrence (weeks) ^a		
Median (Min-Max)	6.1 (0.1-60.1)	3.9 (0.1-30.1)
Q1-Q3	2.1-16.3	1.0-12.4
Time to first occurrence (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	278 (52.6)	169 (82.4)
Median [95% CI]	45.0 [29.9, NE]	NE [NE, NE]
Q1-Q3	6.1-NE	23.1-NE
% Event probability estimate [95% CI]		
Week 12	31.4 [27.6, 35.5]	13.8 [9.6, 19.7]
Week 24	43.0 [38.7, 47.5]	25.6 [17.8, 36.0]
Nausea and Vomiting		
Number of subjects with at least one event, n (%)	209 (39.5)	35 (17.1)
Time to first occurrence (weeks) ^a		
Median (Min-Max)	2.0 (0.1-88.4)	4.9 (0.1-31.1)
Q1-Q3	0.3-10.1	2.0-12.1
Time to first occurrence (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	320 (60.5)	170 (82.9)
Median [95% CI]	NE [88.4, NE]	NE [NE, NE]
Q1-Q3	6.0-NE	26.6-NE
% Event probability estimate [95% CI]		
Week 12	31.2 [27.4, 35.3]	14.1 [9.8, 20.1]
Week 24	36.9 [32.9, 41.3]	22.7 [16.0, 31.6]
Dry mouth		
Number of subjects with at least one event, n (%)	208 (39.3)	2 (1.0)
Time to first occurrence (weeks) ^a		
Median (Min-Max)	5.5 (0.1-47.3)	0.6 (0.1-1.1)
Q1-Q3	0.4-13.1	0.1-1.1
Time to first occurrence (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	321 (60.7)	203 (99.0)
Median [95% CI]	NE [NE, NE]	NE [NE, NE]
Q1-Q3	7.6-NE	NE-NE
% Event probability estimate [95% CI]		
Week 12	28.2 [24.6, 32.3]	1.0 [0.2, 3.9]
Week 24	36.3 [32.3, 40.7]	1.0 [0.2, 3.9]
Hypersensitivity		
Number of subjects with at least one event, n (%)	56 (10.6)	7 (3.4)
Time to first occurrence (weeks) ^a		

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update		Final Version	
Safety Topic of Interest		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Median (Min-Max)		9.0 (0.1-85.1)	13.1 (0.1-19.1)
Q1-Q3		3.2-19.4	0.1-18.1
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		473 (89.4)	198 (96.6)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 12		6.3 [4.5, 8.8]	1.6 [0.5, 4.8]
Week 24		8.7 [6.6, 11.6]	7.3 [3.3, 15.9]
Hepatotoxicity			
Number of subjects with at least one event, n (%)		54 (10.2)	16 (7.8)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		5.8 (0.1-39.9)	3.9 (0.1-15.9)
Q1-Q3		3.0-12.6	0.7-8.2
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		475 (89.8)	189 (92.2)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 12		7.7 [5.7, 10.3]	7.0 [4.1, 11.8]
Week 24		9.4 [7.2, 12.3]	10.6 [6.3, 17.5]
Renal toxicity			
Number of subjects with at least one event, n (%)		46 (8.7)	12 (5.9)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		10.5 (0.1-60.1)	4.9 (0.1-30.3)
Q1-Q3		4.3-24.7	0.2-8.8
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		483 (91.3)	193 (94.1)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 12		4.6 [3.1, 6.8]	5.6 [3.0, 10.1]
Week 24		6.5 [4.7, 9.1]	7.1 [3.7, 13.1]
Late renal toxicity			
Number of subjects with at least one event, n (%)		25 (4.7)	2 (1.0)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		24.1 (12.4-60.1)	23.7 (17.1-30.3)
Q1-Q3		14.0-41.7	17.1-30.3
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		504 (95.3)	203 (99.0)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 12		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 24		2.6 [1.5, 4.6]	1.6 [0.2, 10.6]
Second primary malignancies			
Number of subjects with at least one event, n (%)		12 (2.3)	2 (1.0)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		11.2 (0.7-99.9)	23.4 (23.0-23.9)
Q1-Q3		7.9-16.9	23.0-23.9
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		517 (97.7)	203 (99.0)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update		Final Version	
Safety Topic of Interest		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
% Event probability estimate [95% CI]			
Week 12		1.4 [0.7, 2.8]	0.0 [0.0, 0.0]
Week 24		2.0 [1.1, 3.7]	4.6 [1.2, 17.2]
QT prolongation			
Number of subjects with at least one event, n (%)		9 (1.7)	1 (0.5)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		13.0 (3.4-53.1)	3.4 (3.4-3.4)
Q1-Q3		5.3-36.7	3.4-3.4
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		520 (98.3)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 12		0.8 [0.3, 2.0]	0.5 [0.1, 3.6]
Week 24		1.2 [0.5, 2.7]	0.5 [0.1, 3.6]
Intracranial haemorrhage			
Number of subjects with at least one event, n (%)		7 (1.3)	3 (1.5)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		18.1 (7.0-30.1)	6.1 (3.9-9.7)
Q1-Q3		9.1-27.7	3.9-9.7
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		522 (98.7)	202 (98.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 12		0.6 [0.2, 1.8]	1.8 [0.6, 5.6]
Week 24		1.0 [0.4, 2.5]	1.8 [0.6, 5.6]
Medication errors			
Number of subjects with at least one event, n (%)		1 (0.2)	0
Time to first occurrence (weeks) ^a			
Median (Min-Max)		17.9 (17.9-17.9)	
Q1-Q3		17.9-17.9	
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		528 (99.8)	205 (100)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 12		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 24		0.2 [0.0, 1.6]	0.0 [0.0, 0.0]
Radiotoxicity including inadvertent exposure			
Number of subjects with at least one event, n (%)		1 (0.2)	1 (0.5)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		2.3 (2.3-2.3)	19.4 (19.4-19.4)
Q1-Q3		2.3-2.3	19.4-19.4
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		528 (99.8)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 12		0.2 [0.0, 1.3]	0.0 [0.0, 0.0]
Week 24		0.2 [0.0, 1.3]	1.8 [0.3, 12.0]
Reproductive toxicity			
Number of subjects with at least one event, n (%)		1 (0.2)	0

Safety Topic of Interest	Final Version	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Time to first occurrence (weeks) ^a			
Median (Min-Max)	31.1 (31.1-31.1)		
Q1-Q3	31.1-31.1		
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)	528 (99.8)	205 (100)	
Median [95% CI]	NE [NE, NE]	NE [NE, NE]	
Q1-Q3	NE-NE	NE-NE	
% Event probability estimate [95% CI]			
Week 12	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]	
Week 24	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]	

^a Analysis is based on subjects with at least one event.

^b Analysis is based on all subjects and censors those without an event.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-4 2021-09-22 17:04

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Source data: adsl.xpt, adtte.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Myelosuppression			
Number of patients with at least one event	215 (40.6)	10 (4.9)	225 (30.7)
Anaemia	135 (25.5)	6 (2.9)	141 (19.2)
Thrombocytopenia	83 (15.7)	0	83 (11.3)
Lymphopenia	61 (11.5)	2 (1.0)	63 (8.6)
Leukopenia	58 (11.0)	3 (1.5)	61 (8.3)
Neutropenia	43 (8.1)	2 (1.0)	45 (6.1)
Pancytopenia	6 (1.1)	0	6 (0.8)
Bicytopenia	1 (0.2)	0	1 (0.1)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Febrile neutropenia	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	84 (15.9)	1 (0.5)	85 (11.6)
Anaemia	40 (7.6)	1 (0.5)	41 (5.6)
Lymphopenia	31 (5.9)	0	31 (4.2)
Thrombocytopenia	23 (4.3)	0	23 (3.1)
Neutropenia	11 (2.1)	0	11 (1.5)
Leukopenia	8 (1.5)	0	8 (1.1)
Bicytopenia	1 (0.2)	0	1 (0.1)
Pancytopenia	1 (0.2)	0	1 (0.1)
Grade 4 AEs	16 (3.0)	0	16 (2.2)
Thrombocytopenia	9 (1.7)	0	9 (1.2)
Lymphopenia	3 (0.6)	0	3 (0.4)
Pancytopenia	2 (0.4)	0	2 (0.3)
Anaemia	1 (0.2)	0	1 (0.1)
Leukopenia	1 (0.2)	0	1 (0.1)
Neutropenia	1 (0.2)	0	1 (0.1)
Grade 5 AEs	3 (0.6)	0	3 (0.4)
Pancytopenia	2 (0.4)	0	2 (0.3)
Bone marrow failure	1 (0.2)	0	1 (0.1)
SAEs			
Anaemia	21 (4.0)	0	21 (2.9)
Pancytopenia	11 (2.1)	0	11 (1.5)
Thrombocytopenia	5 (0.9)	0	5 (0.7)
Leukopenia	3 (0.6)	0	3 (0.4)
Bone marrow failure	2 (0.4)	0	2 (0.3)
Febrile neutropenia	1 (0.2)	0	1 (0.1)
Neutropenia	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	33 (6.2)	0	33 (4.5)
Thrombocytopenia	13 (2.5)	0	13 (1.8)
Anaemia	12 (2.3)	0	12 (1.6)
Leukopenia	7 (1.3)	0	7 (1.0)
Neutropenia	4 (0.8)	0	4 (0.5)
Pancytopenia	3 (0.6)	0	3 (0.4)
Lymphopenia	2 (0.4)	0	2 (0.3)
Dose reduced	20 (3.8)	0	20 (2.7)
Thrombocytopenia	9 (1.7)	0	9 (1.2)
Anaemia	7 (1.3)	0	7 (1.0)

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177Lu-PSMA-617 SCS update

Final Version

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Leukopenia	3 (0.6)	0	3 (0.4)
Neutropenia	3 (0.6)	0	3 (0.4)
Lymphopenia	2 (0.4)	0	2 (0.3)
Drug interrupted	46 (8.7)	0	46 (6.3)
Anaemia	23 (4.3)	0	23 (3.1)
Thrombocytopenia	18 (3.4)	0	18 (2.5)
Leukopenia	7 (1.3)	0	7 (1.0)
Neutropenia	4 (0.8)	0	4 (0.5)
Lymphopenia	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	197 (37.2)	10 (4.9)	207 (28.2)
Anaemia	119 (22.5)	6 (2.9)	125 (17.0)
Thrombocytopenia	72 (13.6)	0	72 (9.8)
Lymphopenia	59 (11.2)	2 (1.0)	61 (8.3)
Leukopenia	52 (9.8)	3 (1.5)	55 (7.5)
Neutropenia	40 (7.6)	2 (1.0)	42 (5.7)
Pancytopenia	3 (0.6)	0	3 (0.4)
Bicytopenia	1 (0.2)	0	1 (0.1)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Febrile neutropenia	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	11 (2.1)	0	11 (1.5)
Anaemia	4 (0.8)	0	4 (0.5)
Thrombocytopenia	3 (0.6)	0	3 (0.4)
Leukopenia	2 (0.4)	0	2 (0.3)
Pancytopenia	2 (0.4)	0	2 (0.3)
Dose reduced	0	0	0
Drug interrupted	11 (2.1)	0	11 (1.5)
Anaemia	7 (1.3)	0	7 (1.0)
Thrombocytopenia	3 (0.6)	0	3 (0.4)
Lymphopenia	2 (0.4)	0	2 (0.3)
Leukopenia	1 (0.2)	0	1 (0.1)
Pancytopenia	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	209 (39.5)	10 (4.9)	219 (29.8)
Anaemia	128 (24.2)	6 (2.9)	134 (18.3)
Thrombocytopenia	81 (15.3)	0	81 (11.0)
Lymphopenia	61 (11.5)	2 (1.0)	63 (8.6)
Leukopenia	56 (10.6)	3 (1.5)	59 (8.0)
Neutropenia	43 (8.1)	2 (1.0)	45 (6.1)
Pancytopenia	3 (0.6)	0	3 (0.4)
Bicytopenia	1 (0.2)	0	1 (0.1)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Febrile neutropenia	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	107 (20.2)	4 (2.0)	111 (15.1)
Anaemia	45 (8.5)	2 (1.0)	47 (6.4)
Leukopenia	41 (7.8)	1 (0.5)	42 (5.7)
Neutropenia	28 (5.3)	1 (0.5)	29 (4.0)
Lymphopenia	26 (4.9)	1 (0.5)	27 (3.7)
Thrombocytopenia	24 (4.5)	0	24 (3.3)
Febrile neutropenia	1 (0.2)	0	1 (0.1)
Recovering/resolving	3 (0.6)	0	3 (0.4)
Leukopenia	1 (0.2)	0	1 (0.1)
Lymphopenia	1 (0.2)	0	1 (0.1)
Neutropenia	1 (0.2)	0	1 (0.1)
Thrombocytopenia	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Not recovered/not resolved	153 (28.9)	6 (2.9)	159 (21.7)
Anaemia	91 (17.2)	4 (2.0)	95 (12.9)
Thrombocytopenia	61 (11.5)	0	61 (8.3)
Lymphopenia	39 (7.4)	1 (0.5)	40 (5.4)
Leukopenia	22 (4.2)	2 (1.0)	24 (3.3)
Neutropenia	19 (3.6)	1 (0.5)	20 (2.7)
Bicytopenia	1 (0.2)	0	1 (0.1)
Pancytopenia	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	3 (0.6)	0	3 (0.4)
Anaemia	1 (0.2)	0	1 (0.1)
Neutropenia	1 (0.2)	0	1 (0.1)
Pancytopenia	1 (0.2)	0	1 (0.1)
Fatal	3 (0.6)	0	3 (0.4)
Pancytopenia	2 (0.4)	0	2 (0.3)
Bone marrow failure	1 (0.2)	0	1 (0.1)
Unknown	3 (0.6)	0	3 (0.4)
Pancytopenia	2 (0.4)	0	2 (0.3)
Thrombocytopenia	1 (0.2)	0	1 (0.1)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:09

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Dry mouth			
Number of patients with at least one event	194 (36.7)	1 (0.5)	195 (26.6)
Dry mouth	190 (35.9)	0	190 (25.9)
Aptyalism	2 (0.4)	0	2 (0.3)
Dry throat	1 (0.2)	0	1 (0.1)
Lip dry	1 (0.2)	1 (0.5)	2 (0.3)
Maximum grade			
Grade 3 AEs	0	0	0
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
SAEs	0	0	0
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Dry mouth	1 (0.2)	0	1 (0.1)
Dose reduced	3 (0.6)	0	3 (0.4)
Dry mouth	3 (0.6)	0	3 (0.4)
Drug interrupted	0	0	0
Dose not changed/NA/unknown	191 (36.1)	1 (0.5)	192 (26.2)
Dry mouth	187 (35.3)	0	187 (25.5)
Aptyalism	2 (0.4)	0	2 (0.3)
Dry throat	1 (0.2)	0	1 (0.1)
Lip dry	1 (0.2)	1 (0.5)	2 (0.3)
Action taken with BSC/BSoC			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Dry mouth	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	193 (36.5)	1 (0.5)	194 (26.4)
Dry mouth	189 (35.7)	0	189 (25.7)
Aptyalism	2 (0.4)	0	2 (0.3)
Dry throat	1 (0.2)	0	1 (0.1)
Lip dry	1 (0.2)	1 (0.5)	2 (0.3)
AE outcome			
Recovered/resolved	65 (12.3)	0	65 (8.9)
Dry mouth	64 (12.1)	0	64 (8.7)
Aptyalism	1 (0.2)	0	1 (0.1)
Recovering/resolving	6 (1.1)	0	6 (0.8)
Dry mouth	6 (1.1)	0	6 (0.8)
Not recovered/not resolved	126 (23.8)	1 (0.5)	127 (17.3)
Dry mouth	123 (23.3)	0	123 (16.8)
Aptyalism	1 (0.2)	0	1 (0.1)
Dry throat	1 (0.2)	0	1 (0.1)
Lip dry	1 (0.2)	1 (0.5)	2 (0.3)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	4 (0.8)	0	4 (0.5)
Dry mouth	4 (0.8)	0	4 (0.5)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update		Final Version		
Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Fatigue			
Number of patients with at least one event	190 (35.9)	23 (11.2)	213 (29.0)
Fatigue	165 (31.2)	14 (6.8)	179 (24.4)
Asthenia	24 (4.5)	10 (4.9)	34 (4.6)
Malaise	9 (1.7)	1 (0.5)	10 (1.4)
Lethargy	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	25 (4.7)	0	25 (3.4)
Fatigue	21 (4.0)	0	21 (2.9)
Asthenia	3 (0.6)	0	3 (0.4)
Malaise	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
SAEs			
Fatigue	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	2 (0.4)	0	2 (0.3)
Fatigue	2 (0.4)	0	2 (0.3)
Dose reduced	0	0	0
Drug interrupted	1 (0.2)	0	1 (0.1)
Fatigue	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	189 (35.7)	23 (11.2)	212 (28.9)
Fatigue	164 (31.0)	14 (6.8)	178 (24.3)
Asthenia	24 (4.5)	10 (4.9)	34 (4.6)
Malaise	9 (1.7)	1 (0.5)	10 (1.4)
Lethargy	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	4 (0.8)	0	4 (0.5)
Fatigue	4 (0.8)	0	4 (0.5)
Dose reduced	4 (0.8)	2 (1.0)	6 (0.8)
Fatigue	4 (0.8)	1 (0.5)	5 (0.7)
Asthenia	0	1 (0.5)	1 (0.1)
Drug interrupted	1 (0.2)	0	1 (0.1)
Fatigue	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	184 (34.8)	21 (10.2)	205 (27.9)
Fatigue	158 (29.9)	13 (6.3)	171 (23.3)
Asthenia	24 (4.5)	9 (4.4)	33 (4.5)
Malaise	9 (1.7)	1 (0.5)	10 (1.4)
Lethargy	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	78 (14.7)	6 (2.9)	84 (11.4)
Fatigue	60 (11.3)	2 (1.0)	62 (8.4)
Asthenia	13 (2.5)	3 (1.5)	16 (2.2)
Malaise	7 (1.3)	1 (0.5)	8 (1.1)
Recovering/resolving	4 (0.8)	2 (1.0)	6 (0.8)
Fatigue	3 (0.6)	1 (0.5)	4 (0.5)
Asthenia	1 (0.2)	1 (0.5)	2 (0.3)

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177Lu-PSMA-617 SCS update

Final Version

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Not recovered/not resolved	121 (22.9)	17 (8.3)	138 (18.8)
Fatigue	109 (20.6)	12 (5.9)	121 (16.5)
Asthenia	11 (2.1)	6 (2.9)	17 (2.3)
Malaise	2 (0.4)	0	2 (0.3)
Lethargy	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	0	0	0

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:12

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-sti-rel.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Nausea and Vomiting			
Number of patients with at least one event	162 (30.6)	9 (4.4)	171 (23.3)
Nausea	148 (28.0)	8 (3.9)	156 (21.3)
Vomiting	63 (11.9)	3 (1.5)	66 (9.0)
Maximum grade			
Grade 3 AEs	5 (0.9)	0	5 (0.7)
Nausea	5 (0.9)	0	5 (0.7)
Vomiting	3 (0.6)	0	3 (0.4)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
SAEs	2 (0.4)	0	2 (0.3)
Nausea	2 (0.4)	0	2 (0.3)
Vomiting	2 (0.4)	0	2 (0.3)
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	162 (30.6)	9 (4.4)	171 (23.3)
Nausea	148 (28.0)	8 (3.9)	156 (21.3)
Vomiting	63 (11.9)	3 (1.5)	66 (9.0)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	2 (0.4)	1 (0.5)	3 (0.4)
Nausea	1 (0.2)	1 (0.5)	2 (0.3)
Vomiting	1 (0.2)	0	1 (0.1)
Drug interrupted	2 (0.4)	0	2 (0.3)
Nausea	2 (0.4)	0	2 (0.3)
Dose not changed/NA/unknown	161 (30.4)	8 (3.9)	169 (23.0)
Nausea	146 (27.6)	7 (3.4)	153 (20.8)
Vomiting	62 (11.7)	3 (1.5)	65 (8.9)
AE outcome			
Recovered/resolved	123 (23.3)	5 (2.4)	128 (17.4)
Nausea	102 (19.3)	3 (1.5)	105 (14.3)
Vomiting	50 (9.5)	3 (1.5)	53 (7.2)
Recovering/resolving	2 (0.4)	0	2 (0.3)
Nausea	2 (0.4)	0	2 (0.3)
Not recovered/not resolved	52 (9.8)	4 (2.0)	56 (7.6)
Nausea	49 (9.3)	4 (2.0)	53 (7.2)
Vomiting	17 (3.2)	0	17 (2.3)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	1 (0.2)	0	1 (0.1)
Nausea	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update		Final Version		
Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:14

...\\BIOMETRY\\PROJECTS\\PSMA617VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-sti-ref.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Hepatotoxicity			
Number of patients with at least one event	21 (4.0)	6 (2.9)	27 (3.7)
Aspartate aminotransferase increased	8 (1.5)	3 (1.5)	11 (1.5)
Alanine aminotransferase increased	7 (1.3)	4 (2.0)	11 (1.5)
Blood alkaline phosphatase increased	7 (1.3)	1 (0.5)	8 (1.1)
Hypoalbuminaemia	4 (0.8)	0	4 (0.5)
Gamma-glutamyltransferase increased	2 (0.4)	0	2 (0.3)
Ascites	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	1 (0.2)	1 (0.5)	2 (0.3)
Hyperbilirubinaemia	1 (0.2)	1 (0.5)	2 (0.3)
Transaminases increased	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	4 (0.8)	2 (1.0)	6 (0.8)
Blood alkaline phosphatase increased	2 (0.4)	0	2 (0.3)
Alanine aminotransferase increased	1 (0.2)	1 (0.5)	2 (0.3)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Aspartate aminotransferase increased	0	1 (0.5)	1 (0.1)
Hyperbilirubinaemia	0	1 (0.5)	1 (0.1)
Grade 4 AEs	1 (0.2)	0	1 (0.1)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Grade 5 AEs	0	0	0
SAEs			
Hepatic cytolysis	0	1 (0.5)	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	2 (0.4)	0	2 (0.3)
Alanine aminotransferase increased	1 (0.2)	0	1 (0.1)
Aspartate aminotransferase increased	1 (0.2)	0	1 (0.1)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	20 (3.8)	6 (2.9)	26 (3.5)
Aspartate aminotransferase increased	7 (1.3)	3 (1.5)	10 (1.4)
Blood alkaline phosphatase increased	7 (1.3)	1 (0.5)	8 (1.1)
Alanine aminotransferase increased	6 (1.1)	4 (2.0)	10 (1.4)
Hypoalbuminaemia	4 (0.8)	0	4 (0.5)
Ascites	1 (0.2)	0	1 (0.1)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	1 (0.2)	1 (0.5)	2 (0.3)
Hyperbilirubinaemia	1 (0.2)	1 (0.5)	2 (0.3)
Transaminases increased	0	1 (0.5)	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	1 (0.2)	1 (0.5)	2 (0.3)
Hepatic cytolysis	1 (0.2)	1 (0.5)	2 (0.3)
Dose reduced	0	2 (1.0)	2 (0.3)
Alanine aminotransferase increased	0	1 (0.5)	1 (0.1)
Aspartate aminotransferase increased	0	1 (0.5)	1 (0.1)
Transaminases increased	0	1 (0.5)	1 (0.1)

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177Lu-PSMA-617 SCS update

Final Version

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Drug interrupted	1 (0.2)	1 (0.5)	2 (0.3)
Alanine aminotransferase increased	1 (0.2)	1 (0.5)	2 (0.3)
Aspartate aminotransferase increased	0	1 (0.5)	1 (0.1)
Dose not changed/NA/unknown	20 (3.8)	2 (1.0)	22 (3.0)
Aspartate aminotransferase increased	8 (1.5)	1 (0.5)	9 (1.2)
Blood alkaline phosphatase increased	7 (1.3)	1 (0.5)	8 (1.1)
Alanine aminotransferase increased	6 (1.1)	2 (1.0)	8 (1.1)
Hypoalbuminaemia	4 (0.8)	0	4 (0.5)
Gamma-glutamyltransferase increased	2 (0.4)	0	2 (0.3)
Ascites	1 (0.2)	0	1 (0.1)
Hyperbilirubinaemia	1 (0.2)	1 (0.5)	2 (0.3)
AE outcome			
Recovered/resolved	11 (2.1)	3 (1.5)	14 (1.9)
Aspartate aminotransferase increased	5 (0.9)	2 (1.0)	7 (1.0)
Alanine aminotransferase increased	4 (0.8)	3 (1.5)	7 (1.0)
Blood alkaline phosphatase increased	3 (0.6)	0	3 (0.4)
Ascites	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	1 (0.2)	0	1 (0.1)
Hyperbilirubinaemia	1 (0.2)	0	1 (0.1)
Hypoalbuminaemia	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	10 (1.9)	4 (2.0)	14 (1.9)
Blood alkaline phosphatase increased	5 (0.9)	1 (0.5)	6 (0.8)
Alanine aminotransferase increased	3 (0.6)	1 (0.5)	4 (0.5)
Aspartate aminotransferase increased	3 (0.6)	1 (0.5)	4 (0.5)
Hypoalbuminaemia	3 (0.6)	0	3 (0.4)
Gamma-glutamyltransferase increased	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	0	1 (0.5)	1 (0.1)
Hyperbilirubinaemia	0	1 (0.5)	1 (0.1)
Transaminases increased	0	1 (0.5)	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	0	0	0

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:16

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Hypersensitivity			
Number of patients with at least one event	20 (3.8)	0	20 (2.7)
Stomatitis	6 (1.1)	0	6 (0.8)
Rash	3 (0.6)	0	3 (0.4)
Generalised oedema	2 (0.4)	0	2 (0.3)
Pruritus	2 (0.4)	0	2 (0.3)
Dermatitis acneiform	1 (0.2)	0	1 (0.1)
Erythema	1 (0.2)	0	1 (0.1)
Flushing	1 (0.2)	0	1 (0.1)
Localised oedema	1 (0.2)	0	1 (0.1)
Rash maculo-papular	1 (0.2)	0	1 (0.1)
Sneezing	1 (0.2)	0	1 (0.1)
Swelling face	1 (0.2)	0	1 (0.1)
Swollen tongue	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	1 (0.2)	0	1 (0.1)
Generalised oedema	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
SAEs			
Generalised oedema	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	20 (3.8)	0	20 (2.7)
Stomatitis	6 (1.1)	0	6 (0.8)
Rash	3 (0.6)	0	3 (0.4)
Generalised oedema	2 (0.4)	0	2 (0.3)
Pruritus	2 (0.4)	0	2 (0.3)
Dermatitis acneiform	1 (0.2)	0	1 (0.1)
Erythema	1 (0.2)	0	1 (0.1)
Flushing	1 (0.2)	0	1 (0.1)
Localised oedema	1 (0.2)	0	1 (0.1)
Rash maculo-papular	1 (0.2)	0	1 (0.1)
Sneezing	1 (0.2)	0	1 (0.1)
Swelling face	1 (0.2)	0	1 (0.1)
Swollen tongue	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	1 (0.2)	0	1 (0.1)
Stomatitis	1 (0.2)	0	1 (0.1)
Drug interrupted	0	0	0
Dose not changed/NA/unknown	19 (3.6)	0	19 (2.6)
Stomatitis	5 (0.9)	0	5 (0.7)
Rash	3 (0.6)	0	3 (0.4)
Generalised oedema	2 (0.4)	0	2 (0.3)
Pruritus	2 (0.4)	0	2 (0.3)

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

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Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Dermatitis acneiform	1 (0.2)	0	1 (0.1)
Erythema	1 (0.2)	0	1 (0.1)
Flushing	1 (0.2)	0	1 (0.1)
Localised oedema	1 (0.2)	0	1 (0.1)
Rash maculo-papular	1 (0.2)	0	1 (0.1)
Sneezing	1 (0.2)	0	1 (0.1)
Swelling face	1 (0.2)	0	1 (0.1)
Swollen tongue	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	11 (2.1)	0	11 (1.5)
Stomatitis	4 (0.8)	0	4 (0.5)
Rash	3 (0.6)	0	3 (0.4)
Dermatitis acneiform	1 (0.2)	0	1 (0.1)
Rash maculo-papular	1 (0.2)	0	1 (0.1)
Sneezing	1 (0.2)	0	1 (0.1)
Swollen tongue	1 (0.2)	0	1 (0.1)
Recovering/resolving	1 (0.2)	0	1 (0.1)
Erythema	1 (0.2)	0	1 (0.1)
Not recovered/not resolved	8 (1.5)	0	8 (1.1)
Generalised oedema	2 (0.4)	0	2 (0.3)
Pruritus	2 (0.4)	0	2 (0.3)
Stomatitis	2 (0.4)	0	2 (0.3)
Localised oedema	1 (0.2)	0	1 (0.1)
Swelling face	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	1 (0.2)	0	1 (0.1)
Flushing	1 (0.2)	0	1 (0.1)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:19

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Renal toxicity			
Number of patients with at least one event	18 (3.4)	0	18 (2.5)
Blood creatinine increased	14 (2.6)	0	14 (1.9)
Acute kidney injury	4 (0.8)	0	4 (0.5)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	4 (0.8)	0	4 (0.5)
Acute kidney injury	4 (0.8)	0	4 (0.5)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
SAEs	2 (0.4)	0	2 (0.3)
Acute kidney injury	2 (0.4)	0	2 (0.3)
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	1 (0.2)	0	1 (0.1)
Blood creatinine increased	1 (0.2)	0	1 (0.1)
Drug interrupted	0	0	0
Dose not changed/NA/unknown	17 (3.2)	0	17 (2.3)
Blood creatinine increased	13 (2.5)	0	13 (1.8)
Acute kidney injury	4 (0.8)	0	4 (0.5)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	1 (0.2)	0	1 (0.1)
Blood creatinine increased	1 (0.2)	0	1 (0.1)
Drug interrupted	0	0	0
Dose not changed/NA/unknown	17 (3.2)	0	17 (2.3)
Blood creatinine increased	13 (2.5)	0	13 (1.8)
Acute kidney injury	4 (0.8)	0	4 (0.5)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	9 (1.7)	0	9 (1.2)
Blood creatinine increased	5 (0.9)	0	5 (0.7)
Acute kidney injury	4 (0.8)	0	4 (0.5)
Blood urea increased	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	10 (1.9)	0	10 (1.4)
Blood creatinine increased	10 (1.9)	0	10 (1.4)
Proteinuria	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	0	0	0

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update		Final Version		
Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:22

...\\BIOMETRY\\PROJECTS\\PSMA617VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-sti-ref.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Late renal toxicity			
Number of patients with at least one event	10 (1.9)	0	10 (1.4)
Blood creatinine increased	7 (1.3)	0	7 (1.0)
Acute kidney injury	2 (0.4)	0	2 (0.3)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	2 (0.4)	0	2 (0.3)
Acute kidney injury	2 (0.4)	0	2 (0.3)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
SAEs	1 (0.2)	0	1 (0.1)
Acute kidney injury	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	10 (1.9)	0	10 (1.4)
Blood creatinine increased	7 (1.3)	0	7 (1.0)
Acute kidney injury	2 (0.4)	0	2 (0.3)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	10 (1.9)	0	10 (1.4)
Blood creatinine increased	7 (1.3)	0	7 (1.0)
Acute kidney injury	2 (0.4)	0	2 (0.3)
Blood urea increased	1 (0.2)	0	1 (0.1)
Proteinuria	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	6 (1.1)	0	6 (0.8)
Blood creatinine increased	3 (0.6)	0	3 (0.4)
Acute kidney injury	2 (0.4)	0	2 (0.3)
Blood urea increased	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	5 (0.9)	0	5 (0.7)
Blood creatinine increased	5 (0.9)	0	5 (0.7)
Proteinuria	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	0	0	0

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update		Final Version		
Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:26

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Intracranial haemorrhage			
Number of patients with at least one event	3 (0.6)	0	3 (0.4)
Haemorrhage intracranial	2 (0.4)	0	2 (0.3)
Subdural haematoma	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	0	0	0
Grade 4 AEs	0	0	0
Grade 5 AEs	2 (0.4)	0	2 (0.3)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)
Subdural haematoma	1 (0.2)	0	1 (0.1)
SAEs	3 (0.6)	0	3 (0.4)
Haemorrhage intracranial	2 (0.4)	0	2 (0.3)
Subdural haematoma	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	3 (0.6)	0	3 (0.4)
Haemorrhage intracranial	2 (0.4)	0	2 (0.3)
Subdural haematoma	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	3 (0.6)	0	3 (0.4)
Haemorrhage intracranial	2 (0.4)	0	2 (0.3)
Subdural haematoma	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	0	0	0
Recovering/resolving	0	0	0
Not recovered/not resolved	1 (0.2)	0	1 (0.1)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)
Recovered/resolved with sequelae	0	0	0
Fatal	2 (0.4)	0	2 (0.3)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)
Subdural haematoma	1 (0.2)	0	1 (0.1)
Unknown	0	0	0

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update		Final Version		
Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:30

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
QT prolongation			
Number of patients with at least one event	2 (0.4)	0	2 (0.3)
Syncope	1 (0.2)	0	1 (0.1)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	2 (0.4)	0	2 (0.3)
Syncope	1 (0.2)	0	1 (0.1)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
SAEs	2 (0.4)	0	2 (0.3)
Syncope	1 (0.2)	0	1 (0.1)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	2 (0.4)	0	2 (0.3)
Syncope	1 (0.2)	0	1 (0.1)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)
Syncope	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	2 (0.4)	0	2 (0.3)
Syncope	1 (0.2)	0	1 (0.1)
Ventricular tachycardia	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	0	0	0
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	0	0	0

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 SCS update		Final Version		
Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)	

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:36

...\\BIOMETRY\\PROJECTS\\PSMA617VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-sti-ref.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-5 Incidence of randomized drug-related treatment-emergent safety topics of interest including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Second primary malignancies			
Number of patients with at least one event	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma	1 (0.2)	0	1 (0.1)
Maximum grade			
Grade 3 AEs	0	0	0
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
SAEs	0	0	0
Action taken with PSMA-617			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma	1 (0.2)	0	1 (0.1)
Action taken with BSC/BSoC			
Drug withdrawn	0	0	0
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma	1 (0.2)	0	1 (0.1)
AE outcome			
Recovered/resolved	0	0	0
Recovering/resolving	0	0	0
Not recovered/not resolved	0	0	0
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	1 (0.2)	0	1 (0.1)
Squamous cell carcinoma	1 (0.2)	0	1 (0.1)

Randomized treatment-emergent safety topics = any safety topic that occurred on or after start of randomized treatment up to 30 days after last administration of randomized treatment or prior to the initiation of subsequent anticancer treatment. A patient

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021. Safety topics of interest labelled as 'immediate' (e.g. 'immediate renal toxicity'), include only TEAEs for which onset occurred before 12 weeks of start of study treatment.

Safety topics of interest labelled as 'late' (e.g. 'late renal toxicity'), include only TEAEs for which onset occurred at or after 12 weeks of start of study treatment.

Numbers (n) represent counts of patients.

Output ID: T-2-1-5-5 2021-09-23 15:41

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Fatigue			
Number of patients with at least one event	51 (9.6)	23 (11.2)	74 (10.1)
Fatigue	41 (7.8)	15 (7.3)	56 (7.6)
Asthenia	13 (2.5)	9 (4.4)	22 (3.0)
Malaise	3 (0.6)	1 (0.5)	4 (0.5)
Lethargy	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	7 (1.3)	2 (1.0)	9 (1.2)
Fatigue	7 (1.3)	2 (1.0)	9 (1.2)
Grade 4 AEs	1 (0.2)	0	1 (0.1)
Asthenia	1 (0.2)	0	1 (0.1)
Grade 5 AEs	0	0	0

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6 2021-09-22 17:40

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Myelosuppression			
Number of patients with at least one event	51 (9.6)	19 (9.3)	70 (9.5)
Anaemia	35 (6.6)	15 (7.3)	50 (6.8)
Thrombocytopenia	19 (3.6)	9 (4.4)	28 (3.8)
Lymphopenia	7 (1.3)	1 (0.5)	8 (1.1)
Neutropenia	6 (1.1)	2 (1.0)	8 (1.1)
Pancytopenia	4 (0.8)	0	4 (0.5)
Leukopenia	3 (0.6)	2 (1.0)	5 (0.7)
Maximum grade			
Grade 3 AEs	16 (3.0)	5 (2.4)	21 (2.9)
Anaemia	11 (2.1)	5 (2.4)	16 (2.2)
Pancytopenia	4 (0.8)	0	4 (0.5)
Thrombocytopenia	4 (0.8)	1 (0.5)	5 (0.7)
Lymphopenia	0	1 (0.5)	1 (0.1)
Grade 4 AEs	11 (2.1)	6 (2.9)	17 (2.3)
Thrombocytopenia	8 (1.5)	4 (2.0)	12 (1.6)
Leukopenia	2 (0.4)	1 (0.5)	3 (0.4)
Neutropenia	2 (0.4)	1 (0.5)	3 (0.4)
Anaemia	1 (0.2)	0	1 (0.1)
Grade 5 AEs	0	0	0

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.
Output ID: T-2-1-5-6 2021-09-22 17:42

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Nausea and Vomiting			
Number of patients with at least one event	24 (4.5)	16 (7.8)	40 (5.4)
Nausea	21 (4.0)	14 (6.8)	35 (4.8)
Vomiting	11 (2.1)	7 (3.4)	18 (2.5)
Maximum grade			
Grade 3 AEs	2 (0.4)	0	2 (0.3)
Vomiting	2 (0.4)	0	2 (0.3)
Nausea	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6 2021-09-22 17:42

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Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Hypersensitivity			
Number of patients with at least one event	12 (2.3)	9 (4.4)	21 (2.9)
Rash	4 (0.8)	1 (0.5)	5 (0.7)
Stomatitis	2 (0.4)	2 (1.0)	4 (0.5)
Acute respiratory failure	1 (0.2)	0	1 (0.1)
Anaphylactic reaction	1 (0.2)	0	1 (0.1)
Infusion related reaction	1 (0.2)	0	1 (0.1)
Penile oedema	1 (0.2)	1 (0.5)	2 (0.3)
Pneumonitis	1 (0.2)	0	1 (0.1)
Scrotal oedema	1 (0.2)	1 (0.5)	2 (0.3)
Seasonal allergy	1 (0.2)	0	1 (0.1)
Eczema	0	1 (0.5)	1 (0.1)
Mouth ulceration	0	2 (1.0)	2 (0.3)
Pruritus	0	1 (0.5)	1 (0.1)
Respiratory failure	0	3 (1.5)	3 (0.4)
Maximum grade			
Grade 3 AEs	1 (0.2)	0	1 (0.1)
Anaphylactic reaction	1 (0.2)	0	1 (0.1)
Grade 4 AEs	1 (0.2)	0	1 (0.1)
Pneumonitis	1 (0.2)	0	1 (0.1)
Grade 5 AEs	1 (0.2)	2 (1.0)	3 (0.4)
Acute respiratory failure	1 (0.2)	0	1 (0.1)
Respiratory failure	0	2 (1.0)	2 (0.3)

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6 2021-09-22 17:41

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fu.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Renal toxicity			
Number of patients with at least one event	6 (1.1)	4 (2.0)	10 (1.4)
Acute kidney injury	3 (0.6)	0	3 (0.4)
Renal failure	2 (0.4)	3 (1.5)	5 (0.7)
Blood creatinine increased	1 (0.2)	1 (0.5)	2 (0.3)
Maximum grade			
Grade 3 AEs	2 (0.4)	0	2 (0.3)
Acute kidney injury	1 (0.2)	0	1 (0.1)
Renal failure	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	1 (0.2)	0	1 (0.1)
Acute kidney injury	1 (0.2)	0	1 (0.1)

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6 2021-09-22 17:43

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-sti-fu.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Late renal toxicity			
Number of patients with at least one event	6 (1.1)	4 (2.0)	10 (1.4)
Acute kidney injury	3 (0.6)	0	3 (0.4)
Renal failure	2 (0.4)	3 (1.5)	5 (0.7)
Blood creatinine increased	1 (0.2)	1 (0.5)	2 (0.3)
Maximum grade			
Grade 3 AEs	2 (0.4)	0	2 (0.3)
Acute kidney injury	1 (0.2)	0	1 (0.1)
Renal failure	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	1 (0.2)	0	1 (0.1)
Acute kidney injury	1 (0.2)	0	1 (0.1)

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6 2021-09-22 17:41

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-sti-fu.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Hepatotoxicity			
Number of patients with at least one event	5 (0.9)	5 (2.4)	10 (1.4)
Blood alkaline phosphatase increased	2 (0.4)	1 (0.5)	3 (0.4)
Hypoalbuminaemia	2 (0.4)	0	2 (0.3)
Alanine aminotransferase increased	1 (0.2)	0	1 (0.1)
Aspartate aminotransferase increased	1 (0.2)	0	1 (0.1)
Hepatic enzyme increased	1 (0.2)	0	1 (0.1)
International normalised ratio increased	1 (0.2)	0	1 (0.1)
Acute hepatic failure	0	1 (0.5)	1 (0.1)
Ascites	0	1 (0.5)	1 (0.1)
Cholestasis	0	2 (1.0)	2 (0.3)
Hepatic cytolysis	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	2 (0.4)	1 (0.5)	3 (0.4)
Blood alkaline phosphatase increased	1 (0.2)	0	1 (0.1)
Hepatic enzyme increased	1 (0.2)	0	1 (0.1)
Hepatic cytolysis	0	1 (0.5)	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6 2021-09-22 17:41

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-sti-fu.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Intracranial haemorrhage			
Number of patients with at least one event	4 (0.8)	1 (0.5)	5 (0.7)
Cerebrovascular accident	1 (0.2)	0	1 (0.1)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)
Subarachnoid haemorrhage	1 (0.2)	0	1 (0.1)
Subdural haematoma	1 (0.2)	0	1 (0.1)
Cerebral haemorrhage	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	1 (0.2)	0	1 (0.1)
Subarachnoid haemorrhage	1 (0.2)	0	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	1 (0.2)	1 (0.5)	2 (0.3)
Haemorrhage intracranial	1 (0.2)	0	1 (0.1)
Cerebral haemorrhage	0	1 (0.5)	1 (0.1)

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6 2021-09-22 17:41

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-sti-fu.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Dry mouth			
Number of patients with at least one event	2 (0.4)	1 (0.5)	3 (0.4)
Dry mouth	2 (0.4)	1 (0.5)	3 (0.4)
Maximum grade			
Grade 3 AEs	0	0	0
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6 2021-09-22 17:40

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-stif-u.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 2-1-5-6 Incidence of safety topics of interest during long term follow-up including preferred term level (FAS safety set)

Safety Topic of Interest	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
QT prolongation			
Number of patients with at least one event	1 (0.2)	2 (1.0)	3 (0.4)
Cardiac arrest	1 (0.2)	1 (0.5)	2 (0.3)
Syncope	0	1 (0.5)	1 (0.1)
Maximum grade			
Grade 3 AEs	0	1 (0.5)	1 (0.1)
Syncope	0	1 (0.5)	1 (0.1)
Grade 4 AEs	0	0	0
Grade 5 AEs	1 (0.2)	1 (0.5)	2 (0.3)
Cardiac arrest	1 (0.2)	1 (0.5)	2 (0.3)

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6 2021-09-22 17:43

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-stifuf.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 2-1-5-6s Incidence of safety topics of interest during long term follow-up including preferred term level (Sub-study safety analysis set)

No data to report

Numbers (n) represent counts of patients.

Since no start and end date for AEs were reported in the CRF during long term follow-up, Safety topics of interest labelled as immediate or late are presented in this table irrespective of date of onset.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-5-6s 2021-09-22 17:43

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-ae-sti-fu.sas

Source data: adsl.xpt, adrisk.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 ADR update

Table 2-1-7-1 Adverse drug reactions - randomized treatment-emergent adverse events regardless of study drug relationship, by primary system organ class and ADR group (FAS safety set)

Risk System Organ Class Adverse Drug Reaction	Lu-PSMA-617 +BSC/BSoC (N=529)				BSC/BSoC only (N=205)			
	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3
Blood and lymphatic system disorders								
ADR Anaemia	168 (31.8)	Very Common	68 (12.9)	Very Common	27 (13.2)	Very Common	10 (4.9)	Common
ADR Leukopenia	83 (15.7)	Very Common	22 (4.2)	Common	4 (2.0)	Common	1 (0.5)	Uncommon
ADR Lymphopenia	75 (14.2)	Very Common	41 (7.8)	Common	8 (3.9)	Common	1 (0.5)	Uncommon
ADR Pancytopenia	9 (1.7)	Common	7 (1.3)	Common	0		0	
ADR Thrombocytopenia	91 (17.2)	Very Common	42 (7.9)	Common	9 (4.4)	Common	2 (1.0)	Uncommon
Ear and labyrinth disorders								
ADR Vertigo	11 (2.1)	Common	0		0		0	
Eye disorders								
ADR Dry eye	16 (3.0)	Common	0		2 (1.0)	Uncommon	0	
Gastrointestinal disorders								
ADR Abdominal pain	61 (11.5)	Very Common	7 (1.3)	Common	13 (6.3)	Common	1 (0.5)	Uncommon
ADR Constipation	107 (20.2)	Very Common	6 (1.1)	Common	23 (11.2)	Very Common	1 (0.5)	Uncommon
ADR Diarrhea	101 (19.1)	Very Common	4 (0.8)	Uncommon	6 (2.9)	Common	1 (0.5)	Uncommon
ADR Dry mouth	208 (39.3)	Very Common	0		1 (0.5)	Uncommon	0	
ADR Nausea	188 (35.5)	Very Common	7 (1.3)	Common	34 (16.6)	Very Common	1 (0.5)	Uncommon
ADR Vomiting	101 (19.1)	Very Common	5 (0.9)	Uncommon	13 (6.3)	Common	1 (0.5)	Uncommon
General disorders and administration site conditions								
ADR Decreased appetite	113 (21.4)	Very Common	10 (1.9)	Common	30 (14.6)	Very Common	1 (0.5)	Uncommon
ADR Fatigue	228 (43.1)	Very Common	31 (5.9)	Common	47 (22.9)	Very Common	3 (1.5)	Common
ADR Oedema peripheral	52 (9.8)	Common	2 (0.4)	Uncommon	14 (6.8)	Common	1 (0.5)	Uncommon
ADR Pyrexia	37 (7.0)	Common	2 (0.4)	Uncommon	7 (3.4)	Common	0	
ADR Weight decreased	58 (11.0)	Very Common	2 (0.4)	Uncommon	20 (9.8)	Common	1 (0.5)	Uncommon
Nervous system disorders								

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 ADR update

Final Version

Risk System Organ Class Adverse Drug Reaction	Lu-PSMA-617 +BSC/BSoc (N=529)				BSC/BSoC only (N=205)			
	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3
ADR Dizziness	44 (8.3)	Common	5 (0.9)	Uncommon	9 (4.4)	Common	0	
ADR Dysgeusia	37 (7.0)	Common	0		3 (1.5)	Common	0	
ADR Headache	37 (7.0)	Common	4 (0.8)	Uncommon	4 (2.0)	Common	0	
Renal and urinary disorders								
ADR Acute kidney injury	45 (8.5)	Common	17 (3.2)	Common	12 (5.9)	Common	6 (2.9)	Common
ADR Urinary tract infection	62 (11.7)	Very Common	20 (3.8)	Common	2 (1.0)	Uncommon	1 (0.5)	Uncommon

Numbers (n) represent counts of subjects.

A subject with multiple severity grades for events contributing to an ADR is only counted under the maximum grade.

Frequency category is based on the following convention: very common (>=1/10); common (>=1/100 to <1/10); uncommon (>=1/1,000 to <1/100); rare (>=1/10,000 to <1/1,000); very rare (<1/10,000).

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-2-1-7-1 2021-09-22 17:04

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-teae-soc-adr.sas

Source data: adsl.xpt, adadr.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-1-1 Worst post-baseline hematology abnormalities during randomized treatment based on CTC grades (FAS safety set)

	Lu-PSMA-617+BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All Grades n (%)	Grades 3/4 n (%)	All Grades n (%)	Grades 3/4 n (%)	All Grades n (%)	Grades 3/4 n (%)
Eosinophils (10E9/L) - Eosinophilia	37 (7.0)	0	19 (9.3)	0	56 (7.6)	0
Hemoglobin (g/L) - Anemia	520 (98.3)	80 (15.1)	179 (87.3)	13 (6.3)	699 (95.2)	93 (12.7)
Hemoglobin (g/L) - Increased	1 (0.2)	0	0	0	1 (0.1)	0
Leukocytes (10E9/L) - Decreased	307 (58.0)	36 (6.8)	54 (26.3)	4 (2.0)	361 (49.2)	40 (5.4)
Lymphocytes (10E9/L) - Decreased	480 (90.7)	269 (50.9)	141 (68.8)	39 (19.0)	621 (84.6)	308 (42.0)
Lymphocytes (10E9/L) - Increased	2 (0.4)	2 (0.4)	2 (1.0)	0	4 (0.5)	2 (0.3)
Neutrophils (10E9/L) - Decreased	149 (28.2)	23 (4.3)	20 (9.8)	2 (1.0)	169 (23.0)	25 (3.4)
Platelets (10E9/L) - Decreased	258 (48.8)	49 (9.3)	49 (23.9)	5 (2.4)	307 (41.8)	54 (7.4)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

All grades' represents patients with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-1 2021-09-22 16:59

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-worstctcae.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-1-1s Worst post-baseline hematology abnormalities during study treatment based on CTC grades (Sub-study safety analysis set)

	Lu-PSMA-617+BSC/BSoC (N=30)	
	All Grades n (%)	Grades 3/4 n (%)
Eosinophils (10E9/L) - Eosinophilia	2 (6.7)	0
Hemoglobin (g/L) - Anemia	26 (86.7)	2 (6.7)
Leukocytes (10E9/L) - Decreased	10 (33.3)	2 (6.7)
Lymphocytes (10E9/L) - Decreased	28 (93.3)	7 (23.3)
Neutrophils (10E9/L) - Decreased	6 (20.0)	0
Platelets (10E9/L) - Decreased	11 (36.7)	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

All grades' represents patients with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-1-1s 2021-09-22 16:59

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-worstctcae.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 3-2-1-2 Hematology shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Eosinophils (10E9/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	483 (91.3)	452 (93.6)	27 (5.6)	0	0	0	4 (0.8)
		Grade 1	15 (2.8)	5 (33.3)	10 (66.7)	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	31 (5.9)	28 (90.3)	0	0	0	0	3 (9.7)
		Total	529 (100)	485 (91.7)	37 (7.0)	0	0	0	7 (1.3)
	BSC/BSoC only (N=205)	Grade 0	198 (96.6)	173 (87.4)	14 (7.1)	0	0	0	11 (5.6)
		Grade 1	6 (2.9)	1 (16.7)	5 (83.3)	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	1 (0.5)	1 (100)	0	0	0	0	0
		Total	205 (100)	175 (85.4)	19 (9.3)	0	0	0	11 (5.4)
Overall (N=734)		Grade 0	681 (92.8)	625 (91.8)	41 (6.0)	0	0	0	15 (2.2)
		Grade 1	21 (2.9)	6 (28.6)	15 (71.4)	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	32 (4.4)	29 (90.6)	0	0	0	0	3 (9.4)
		Total	734 (100)	660 (89.9)	56 (7.6)	0	0	0	18 (2.5)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-2 2021-09-22 16:56

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-shiftctc.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 3-2-1-2 Hematology shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Hemoglobin (g/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	119 (22.5)	9 (7.6)	93 (78.2)	14 (11.8)	3 (2.5)	0	0
		Grade 1	350 (66.2)	0	158 (45.1)	150 (42.9)	42 (12.0)	0	0
		Grade 2	59 (11.2)	0	2 (3.4)	23 (39.0)	34 (57.6)	0	0
		Grade 3	1 (0.2)	0	0	0	1 (100)	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	9 (1.7)	253 (47.8)	187 (35.3)	80 (15.1)	0	0
	BSC/BSoC only (N=205)	Grade 0	38 (18.5)	17 (44.7)	19 (50.0)	1 (2.6)	0	0	1 (2.6)
		Grade 1	131 (63.9)	2 (1.5)	83 (63.4)	35 (26.7)	7 (5.3)	0	4 (3.1)
		Grade 2	36 (17.6)	0	0	28 (77.8)	6 (16.7)	0	2 (5.6)
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	19 (9.3)	102 (49.8)	64 (31.2)	13 (6.3)	0	7 (3.4)
Overall (N=734)	Overall (N=734)	Grade 0	157 (21.4)	26 (16.6)	112 (71.3)	15 (9.6)	3 (1.9)	0	1 (0.6)
		Grade 1	481 (65.5)	2 (0.4)	241 (50.1)	185 (38.5)	49 (10.2)	0	4 (0.8)
		Grade 2	95 (12.9)	0	2 (2.1)	51 (53.7)	40 (42.1)	0	2 (2.1)
		Grade 3	1 (0.1)	0	0	0	1 (100)	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	28 (3.8)	355 (48.4)	251 (34.2)	93 (12.7)	0	7 (1.0)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-2 2021-09-22 16:56

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-shiftctc.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 3-2-1-2 Hematology shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Hemoglobin (g/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	529 (100)	528 (99.8)	1 (0.2)	0	0	0	0
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	528 (99.8)	1 (0.2)	0	0	0	0
	BSC/BSoC only (N=205)	Grade 0	205 (100)	198 (96.6)	0	0	0	0	7 (3.4)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	198 (96.6)	0	0	0	0	7 (3.4)
Overall (N=734)	Overall (N=734)	Grade 0	734 (100)	726 (98.9)	1 (0.1)	0	0	0	7 (1.0)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	726 (98.9)	1 (0.1)	0	0	0	7 (1.0)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-2 2021-09-22 16:56

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-shiftctc.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-1-2 Hematology shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Lymphocytes (10E9/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	296 (56.0)	41 (13.9)	42 (14.2)	121 (40.9)	86 (29.1)	5 (1.7)	1 (0.3)
		Grade 1	79 (14.9)	0	5 (6.3)	28 (35.4)	41 (51.9)	4 (5.1)	1 (1.3)
		Grade 2	104 (19.7)	0	1 (1.0)	9 (8.7)	82 (78.8)	11 (10.6)	1 (1.0)
		Grade 3	28 (5.3)	0	0	0	20 (71.4)	8 (28.6)	0
		Grade 4	2 (0.4)	0	0	1 (50.0)	1 (50.0)	0	0
		Missing	20 (3.8)	3 (15.0)	0	4 (20.0)	11 (55.0)	0	2 (10.0)
		Total	529 (100)	44 (8.3)	48 (9.1)	163 (30.8)	241 (45.6)	28 (5.3)	5 (0.9)
	BSC/BSoC only (N=205)	Grade 0	112 (54.6)	47 (42.0)	22 (19.6)	24 (21.4)	12 (10.7)	2 (1.8)	5 (4.5)
		Grade 1	36 (17.6)	6 (16.7)	7 (19.4)	18 (50.0)	3 (8.3)	0	2 (5.6)
		Grade 2	47 (22.9)	0	3 (6.4)	26 (55.3)	17 (36.2)	0	1 (2.1)
		Grade 3	9 (4.4)	0	0	2 (22.2)	4 (44.4)	0	3 (33.3)
		Grade 4	1 (0.5)	0	0	0	1 (100)	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	53 (25.9)	32 (15.6)	70 (34.1)	37 (18.0)	2 (1.0)	11 (5.4)
Overall (N=734)	Overall (N=734)	Grade 0	408 (55.6)	88 (21.6)	64 (15.7)	145 (35.5)	98 (24.0)	7 (1.7)	6 (1.5)
		Grade 1	115 (15.7)	6 (5.2)	12 (10.4)	46 (40.0)	44 (38.3)	4 (3.5)	3 (2.6)
		Grade 2	151 (20.6)	0	4 (2.6)	35 (23.2)	99 (65.6)	11 (7.3)	2 (1.3)
		Grade 3	37 (5.0)	0	0	2 (5.4)	24 (64.9)	8 (21.6)	3 (8.1)
		Grade 4	3 (0.4)	0	0	1 (33.3)	2 (66.7)	0	0
		Missing	20 (2.7)	3 (15.0)	0	4 (20.0)	11 (55.0)	0	2 (10.0)
		Total	734 (100)	97 (13.2)	80 (10.9)	233 (31.7)	278 (37.9)	30 (4.1)	16 (2.2)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-2 2021-09-22 16:56

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Final Version

177Lu-PSMA-617 SCS update

Table 3-2-1-2 Hematology shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Lymphocytes (10E9/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	509 (96.2)	504 (99.0)	0	0	2 (0.4)	0	3 (0.6)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	20 (3.8)	18 (90.0)	0	0	0	0	2 (10.0)
		Total	529 (100)	522 (98.7)	0	0	2 (0.4)	0	5 (0.9)
	BSC/BSoC only (N=205)	Grade 0	204 (99.5)	191 (93.6)	0	2 (1.0)	0	0	11 (5.4)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	1 (0.5)	1 (100)	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
Overall (N=734)	Overall (N=734)	Total	205 (100)	192 (93.7)	0	2 (1.0)	0	0	11 (5.4)
		Grade 0	713 (97.1)	695 (97.5)	0	2 (0.3)	2 (0.3)	0	14 (2.0)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	1 (0.1)	1 (100)	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	20 (2.7)	18 (90.0)	0	0	0	0	2 (10.0)
		Total	734 (100)	714 (97.3)	0	2 (0.3)	2 (0.3)	0	16 (2.2)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-2 2021-09-22 16:56

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Final Version

177Lu-PSMA-617 SCS update

Table 3-2-1-2 Hematology shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Neutrophils (10E9/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	490 (92.6)	357 (72.9)	56 (11.4)	56 (11.4)	18 (3.7)	0	3 (0.6)
		Grade 1	13 (2.5)	3 (23.1)	5 (38.5)	5 (38.5)	0	0	0
		Grade 2	8 (1.5)	0	0	3 (37.5)	3 (37.5)	2 (25.0)	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	18 (3.4)	15 (83.3)	0	1 (5.6)	0	0	2 (11.1)
		Total	529 (100)	375 (70.9)	61 (11.5)	65 (12.3)	21 (4.0)	2 (0.4)	5 (0.9)
	BSC/BSoC only (N=205)	Grade 0	198 (96.6)	174 (87.9)	11 (5.6)	4 (2.0)	0	1 (0.5)	8 (4.0)
		Grade 1	4 (2.0)	2 (50.0)	1 (25.0)	1 (25.0)	0	0	0
		Grade 2	2 (1.0)	0	0	1 (50.0)	0	0	1 (50.0)
		Grade 3	1 (0.5)	0	0	0	1 (100)	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	176 (85.9)	12 (5.9)	6 (2.9)	1 (0.5)	1 (0.5)	9 (4.4)
Overall (N=734)		Grade 0	688 (93.7)	531 (77.2)	67 (9.7)	60 (8.7)	18 (2.6)	1 (0.1)	11 (1.6)
		Grade 1	17 (2.3)	5 (29.4)	6 (35.3)	6 (35.3)	0	0	0
		Grade 2	10 (1.4)	0	0	4 (40.0)	3 (30.0)	2 (20.0)	1 (10.0)
		Grade 3	1 (0.1)	0	0	0	1 (100)	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	18 (2.5)	15 (83.3)	0	1 (5.6)	0	0	2 (11.1)
		Total	734 (100)	551 (75.1)	73 (9.9)	71 (9.7)	22 (3.0)	3 (0.4)	14 (1.9)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-2 2021-09-22 16:56

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177Lu-PSMA-617 SCS update

Final Version

Table 3-2-1-2 Hematology shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Platelets (10E9/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	486 (91.9)	271 (55.8)	153 (31.5)	27 (5.6)	27 (5.6)	8 (1.6)	0
		Grade 1	39 (7.4)	0	21 (53.8)	7 (17.9)	9 (23.1)	2 (5.1)	0
		Grade 2	3 (0.6)	0	1 (33.3)	0	1 (33.3)	1 (33.3)	0
		Grade 3	1 (0.2)	0	0	0	0	1 (100)	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	271 (51.2)	175 (33.1)	34 (6.4)	37 (7.0)	12 (2.3)	0
	BSC/BSoC only (N=205)	Grade 0	184 (89.8)	147 (79.9)	31 (16.8)	2 (1.1)	0	1 (0.5)	3 (1.6)
		Grade 1	18 (8.8)	2 (11.1)	8 (44.4)	2 (11.1)	3 (16.7)	0	3 (16.7)
		Grade 2	3 (1.5)	0	0	1 (33.3)	0	1 (33.3)	1 (33.3)
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	149 (72.7)	39 (19.0)	5 (2.4)	3 (1.5)	2 (1.0)	7 (3.4)
Overall (N=734)	Overall (N=734)	Grade 0	670 (91.3)	418 (62.4)	184 (27.5)	29 (4.3)	27 (4.0)	9 (1.3)	3 (0.4)
		Grade 1	57 (7.8)	2 (3.5)	29 (50.9)	9 (15.8)	12 (21.1)	2 (3.5)	3 (5.3)
		Grade 2	6 (0.8)	0	1 (16.7)	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)
		Grade 3	1 (0.1)	0	0	0	0	1 (100)	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	420 (57.2)	214 (29.2)	39 (5.3)	40 (5.4)	14 (1.9)	7 (1.0)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-2 2021-09-22 16:56

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Source data: adlb.xpt, adsl.xpt

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-1-2 Hematology shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Leukocytes (10E9/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	475 (89.8)	222 (46.7)	138 (29.1)	96 (20.2)	18 (3.8)	1 (0.2)	0
		Grade 1	43 (8.1)	0	10 (23.3)	24 (55.8)	9 (20.9)	0	0
		Grade 2	11 (2.1)	0	0	3 (27.3)	7 (63.6)	1 (9.1)	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	222 (42.0)	148 (28.0)	123 (23.3)	34 (6.4)	2 (0.4)	0
	BSC/BSoC only (N=205)	Grade 0	185 (90.2)	143 (77.3)	25 (13.5)	7 (3.8)	3 (1.6)	1 (0.5)	6 (3.2)
		Grade 1	15 (7.3)	1 (6.7)	6 (40.0)	8 (53.3)	0	0	0
		Grade 2	5 (2.4)	0	1 (20.0)	3 (60.0)	0	0	1 (20.0)
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	144 (70.2)	32 (15.6)	18 (8.8)	3 (1.5)	1 (0.5)	7 (3.4)
Overall (N=734)	Overall (N=734)	Grade 0	660 (89.9)	365 (55.3)	163 (24.7)	103 (15.6)	21 (3.2)	2 (0.3)	6 (0.9)
		Grade 1	58 (7.9)	1 (1.7)	16 (27.6)	32 (55.2)	9 (15.5)	0	0
		Grade 2	16 (2.2)	0	1 (6.3)	6 (37.5)	7 (43.8)	1 (6.3)	1 (6.3)
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	366 (49.9)	180 (24.5)	141 (19.2)	37 (5.0)	3 (0.4)	7 (1.0)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-2 2021-09-22 16:56

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177Lu-PSMA-617 SCS update

Final Version

Table 3-2-1-2s Hematology shift table during study treatment based on CTC grades (Sub-study safety analysis set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Eosinophils (10E9/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	30 (100)	27 (90.0)	2 (6.7)	0	0	0	1 (3.3)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	27 (90.0)	2 (6.7)	0	0	0	1 (3.3)
Hemoglobin (g/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	6 (20.0)	3 (50.0)	3 (50.0)	0	0	0	0
		Grade 1	22 (73.3)	0	13 (59.1)	7 (31.8)	1 (4.5)	0	1 (4.5)
		Grade 2	2 (6.7)	0	0	1 (50.0)	1 (50.0)	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	3 (10.0)	16 (53.3)	8 (26.7)	2 (6.7)	0	1 (3.3)
Hemoglobin (g/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	30 (100)	29 (96.7)	0	0	0	0	1 (3.3)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	29 (96.7)	0	0	0	0	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

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177Lu-PSMA-617 SCS update

Final Version

Table 3-2-1-2s Hematology shift table during study treatment based on CTC grades (Sub-study safety analysis set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Lymphocytes (10E9/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	14 (46.7)	1 (7.1)	6 (42.9)	6 (42.9)	1 (7.1)	0	0
		Grade 1	10 (33.3)	0	1 (10.0)	6 (60.0)	2 (20.0)	0	1 (10.0)
		Grade 2	5 (16.7)	0	0	2 (40.0)	3 (60.0)	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	1 (3.3)	0	0	0	0	1 (100)	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	1 (3.3)	7 (23.3)	14 (46.7)	6 (20.0)	1 (3.3)	1 (3.3)
Lymphocytes (10E9/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	30 (100)	29 (96.7)	0	0	0	0	1 (3.3)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	29 (96.7)	0	0	0	0	1 (3.3)
Neutrophils (10E9/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	28 (93.3)	23 (82.1)	1 (3.6)	3 (10.7)	0	0	1 (3.6)
		Grade 1	2 (6.7)	0	0	2 (100)	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	23 (76.7)	1 (3.3)	5 (16.7)	0	0	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-1-2s 2021-09-22 16:56

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177Lu-PSMA-617 SCS update

Final Version

Table 3-2-1-2s Hematology shift table during study treatment based on CTC grades (Sub-study safety analysis set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Platelets (10E9/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	29 (96.7)	17 (58.6)	9 (31.0)	1 (3.4)	0	1 (3.4)	1 (3.4)
		Grade 1	1 (3.3)	1 (100)	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	18 (60.0)	9 (30.0)	1 (3.3)	0	1 (3.3)	1 (3.3)
Leukocytes (10E9/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	28 (93.3)	19 (67.9)	6 (21.4)	2 (7.1)	0	0	1 (3.6)
		Grade 1	2 (6.7)	0	0	0	2 (100)	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	19 (63.3)	6 (20.0)	2 (6.7)	2 (6.7)	0	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

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Source data: adlb.xpt, adsl.xpt

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Table 3-2-1-3 Worst post-baseline hematology abnormalities during long-term follow up based on CTC grades (FAS safety set)

	Lu-PSMA-617+BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All Grades n (%)	Grades 3/4 n (%)	All Grades n (%)	Grades 3/4 n (%)	All Grades n (%)	Grades 3/4 n (%)
Eosinophils (10E9/L) - Eosinophilia	3 (0.6)	0	4 (2.0)	0	7 (1.0)	0
Hemoglobin (g/L) - Anemia	163 (30.8)	44 (8.3)	71 (34.6)	14 (6.8)	234 (31.9)	58 (7.9)
Leukocytes (10E9/L) - Decreased	74 (14.0)	11 (2.1)	19 (9.3)	4 (2.0)	93 (12.7)	15 (2.0)
Lymphocytes (10E9/L) - Decreased	122 (23.1)	43 (8.1)	52 (25.4)	25 (12.2)	174 (23.7)	68 (9.3)
Neutrophils (10E9/L) - Decreased	36 (6.8)	8 (1.5)	8 (3.9)	2 (1.0)	44 (6.0)	10 (1.4)
Platelets (10E9/L) - Decreased	92 (17.4)	32 (6.0)	29 (14.1)	8 (3.9)	121 (16.5)	40 (5.4)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

All grades' represents patients with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-1-3 2021-09-22 16:59

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-worstctcae.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-2-1 Worst post-baseline chemistry abnormalities during randomized treatment based on CTC grades (FAS safety set)

	Lu-PSMA-617+BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All Grades n (%)	Grades 3/4 n (%)	All Grades n (%)	Grades 3/4 n (%)	All Grades n (%)	Grades 3/4 n (%)
Alanine aminotransferase (IU/L) - Increased	104 (19.7)	8 (1.5)	30 (14.6)	2 (1.0)	134 (18.3)	10 (1.4)
Albumin (g/L) - Hypoalbuminemia	240 (45.4)	3 (0.6)	81 (39.5)	0	321 (43.7)	3 (0.4)
Alkaline phosphatase (IU/L) - Increased	138 (26.1)	4 (0.8)	50 (24.4)	2 (1.0)	188 (25.6)	6 (0.8)
Aspartate aminotransferase (IU/L) - Increased	167 (31.6)	6 (1.1)	43 (21.0)	2 (1.0)	210 (28.6)	8 (1.1)
Bilirubin (umol/L) - Increased	52 (9.8)	4 (0.8)	28 (13.7)	1 (0.5)	80 (10.9)	5 (0.7)
Calcium (mmol/L) - Hypercalcemia	57 (10.8)	3 (0.6)	14 (6.8)	1 (0.5)	71 (9.7)	4 (0.5)
Calcium (mmol/L) - Hypocalcemia	231 (43.7)	13 (2.5)	65 (31.7)	6 (2.9)	296 (40.3)	19 (2.6)
Creatinine (umol/L) - Increased	162 (30.6)	5 (0.9)	47 (22.9)	1 (0.5)	209 (28.5)	6 (0.8)
Glucose (mmol/L) - Hypoglycemia	51 (9.6)	0	11 (5.4)	0	62 (8.4)	0
Lactate dehydrogenase (IU/L) - Increased	355 (67.1)	0	123 (60.0)	0	478 (65.1)	0
Potassium (mmol/L) - Hyperkalemia	136 (25.7)	3 (0.6)	39 (19.0)	1 (0.5)	175 (23.8)	4 (0.5)
Potassium (mmol/L) - Hypokalemia	90 (17.0)	7 (1.3)	34 (16.6)	0	124 (16.9)	7 (1.0)
Sodium (mmol/L) - Hypernatremia	60 (11.3)	0	12 (5.9)	0	72 (9.8)	0
Sodium (mmol/L) - Hyponatremia	205 (38.8)	4 (0.8)	51 (24.9)	2 (1.0)	256 (34.9)	6 (0.8)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

All grades' represents patients with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2-1 2021-09-22 16:59

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-worstctcae.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-1s Worst post-baseline chemistry abnormalities during study treatment based on CTC grades (Sub-study safety analysis set)

	Lu-PSMA-617+BSC/BSoC (N=30)	
	All Grades n (%)	Grades 3/4 n (%)
Alanine aminotransferase (IU/L) - Increased	2 (6.7)	0
Albumin (g/L) - Hypoalbuminemia	5 (16.7)	0
Alkaline phosphatase (IU/L) - Increased	11 (36.7)	0
Aspartate aminotransferase (IU/L) - Increased	11 (36.7)	0
Bilirubin (umol/L) - Increased	2 (6.7)	0
Calcium (mmol/L) - Hypocalcemia	10 (33.3)	0
Creatinine (umol/L) - Increased	6 (20.0)	0
Glucose (mmol/L) - Hypoglycemia	9 (30.0)	1 (3.3)
Lactate dehydrogenase (IU/L) - Increased	25 (83.3)	0
Potassium (mmol/L) - Hyperkalemia	11 (36.7)	2 (6.7)
Potassium (mmol/L) - Hypokalemia	2 (6.7)	0
Sodium (mmol/L) - Hypernatremia	1 (3.3)	0
Sodium (mmol/L) - Hyponatremia	3 (10.0)	0

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

All grades' represents patients with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-2-1s 2021-09-22 17:00

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\PGM\\t-lb-worstctcae.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value				
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Albumin (g/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	445 (84.1)	285 (64.0)	130 (29.2)	28 (6.3)	1 (0.2)	0
		Grade 1	72 (13.6)	3 (4.2)	41 (56.9)	26 (36.1)	2 (2.8)	0
		Grade 2	12 (2.3)	0	3 (25.0)	9 (75.0)	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Missing	0	0	0	0	0	0
	BSC/BSoC only (N=205)	Total	529 (100)	288 (54.4)	174 (32.9)	63 (11.9)	3 (0.6)	0
		Grade 0	180 (87.8)	116 (64.4)	45 (25.0)	13 (7.2)	0	6 (3.3)
		Grade 1	22 (10.7)	0	12 (54.5)	10 (45.5)	0	0
		Grade 2	3 (1.5)	1 (33.3)	1 (33.3)	0	0	1 (33.3)
Overall (N=734)	Overall (N=734)	Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Missing	0	0	0	0	0	0
		Total	205 (100)	117 (57.1)	58 (28.3)	23 (11.2)	0	7 (3.4)
		Grade 0	625 (85.1)	401 (64.2)	175 (28.0)	41 (6.6)	1 (0.2)	0
		Grade 1	94 (12.8)	3 (3.2)	53 (56.4)	36 (38.3)	2 (2.1)	0
		Grade 2	15 (2.0)	1 (6.7)	4 (26.7)	9 (60.0)	0	1 (6.7)
	Grade 3	0	0	0	0	0	0	0
	Grade 4	0	0	0	0	0	0	0
	Missing	0	0	0	0	0	0	0
	Total	734 (100)	405 (55.2)	232 (31.6)	86 (11.7)	3 (0.4)	0	8 (1.1)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Alkaline phosphatase (IU/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	300 (56.7)	212 (70.7)	75 (25.0)	11 (3.7)	2 (0.7)	0	0
		Grade 1	162 (30.6)	120 (74.1)	17 (10.5)	22 (13.6)	2 (1.2)	0	1 (0.6)
		Grade 2	43 (8.1)	37 (86.0)	2 (4.7)	4 (9.3)	0	0	0
		Grade 3	23 (4.3)	21 (91.3)	1 (4.3)	1 (4.3)	0	0	0
		Grade 4	1 (0.2)	0	0	1 (100)	0	0	0
		Missing	0	0	0	0	0	0	0
	BSC/BSoC only (N=205)	Total	529 (100)	390 (73.7)	95 (18.0)	39 (7.4)	4 (0.8)	0	1 (0.2)
		Grade 0	125 (61.0)	85 (68.0)	31 (24.8)	4 (3.2)	1 (0.8)	0	4 (3.2)
		Grade 1	56 (27.3)	40 (71.4)	7 (12.5)	4 (7.1)	1 (1.8)	0	4 (7.1)
		Grade 2	14 (6.8)	12 (85.7)	2 (14.3)	0	0	0	0
		Grade 3	10 (4.9)	10 (100)	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	147 (71.7)	40 (19.5)	8 (3.9)	2 (1.0)	0	8 (3.9)
	Overall (N=734)	Grade 0	425 (57.9)	297 (69.9)	106 (24.9)	15 (3.5)	3 (0.7)	0	4 (0.9)
		Grade 1	218 (29.7)	160 (73.4)	24 (11.0)	26 (11.9)	3 (1.4)	0	5 (2.3)
		Grade 2	57 (7.8)	49 (86.0)	4 (7.0)	4 (7.0)	0	0	0
		Grade 3	33 (4.5)	31 (93.9)	1 (3.0)	1 (3.0)	0	0	0
		Grade 4	1 (0.1)	0	0	1 (100)	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	537 (73.2)	135 (18.4)	47 (6.4)	6 (0.8)	0	9 (1.2)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Alanine aminotransferase (IU/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	504 (95.3)	405 (80.4)	75 (14.9)	15 (3.0)	7 (1.4)	1 (0.2)	1 (0.2)
		Grade 1	24 (4.5)	18 (75.0)	3 (12.5)	3 (12.5)	0	0	0
		Grade 2	1 (0.2)	1 (100)	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	424 (80.2)	78 (14.7)	18 (3.4)	7 (1.3)	1 (0.2)	1 (0.2)
	BSC/BSoC only (N=205)	Grade 0	199 (97.1)	163 (81.9)	24 (12.1)	3 (1.5)	2 (1.0)	0	7 (3.5)
		Grade 1	5 (2.4)	4 (80.0)	0	1 (20.0)	0	0	0
		Grade 2	1 (0.5)	1 (100)	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	168 (82.0)	24 (11.7)	4 (2.0)	2 (1.0)	0	7 (3.4)
	Overall (N=734)	Grade 0	703 (95.8)	568 (80.8)	99 (14.1)	18 (2.6)	9 (1.3)	1 (0.1)	8 (1.1)
		Grade 1	29 (4.0)	22 (75.9)	3 (10.3)	4 (13.8)	0	0	0
		Grade 2	2 (0.3)	2 (100)	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	592 (80.7)	102 (13.9)	22 (3.0)	9 (1.2)	1 (0.1)	8 (1.1)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2 2021-09-22 16:57

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-shiftctc.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Aspartate aminotransferase (IU/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	461 (87.1)	316 (68.5)	127 (27.5)	11 (2.4)	4 (0.9)	1 (0.2)	2 (0.4)
		Grade 1	64 (12.1)	40 (62.5)	16 (25.0)	6 (9.4)	1 (1.6)	0	1 (1.6)
		Grade 2	3 (0.6)	2 (66.7)	1 (33.3)	0	0	0	0
		Grade 3	1 (0.2)	1 (100)	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	359 (67.9)	144 (27.2)	17 (3.2)	5 (0.9)	1 (0.2)	3 (0.6)
	BSC/BSoC only (N=205)	Grade 0	170 (82.9)	133 (78.2)	28 (16.5)	1 (0.6)	2 (1.2)	0	6 (3.5)
		Grade 1	31 (15.1)	17 (54.8)	8 (25.8)	4 (12.9)	0	0	2 (6.5)
		Grade 2	3 (1.5)	3 (100)	0	0	0	0	0
		Grade 3	1 (0.5)	1 (100)	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	154 (75.1)	36 (17.6)	5 (2.4)	2 (1.0)	0	8 (3.9)
Overall (N=734)	Overall (N=734)	Grade 0	631 (86.0)	449 (71.2)	155 (24.6)	12 (1.9)	6 (1.0)	1 (0.2)	8 (1.3)
		Grade 1	95 (12.9)	57 (60.0)	24 (25.3)	10 (10.5)	1 (1.1)	0	3 (3.2)
		Grade 2	6 (0.8)	5 (83.3)	1 (16.7)	0	0	0	0
		Grade 3	2 (0.3)	2 (100)	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	513 (69.9)	180 (24.5)	22 (3.0)	7 (1.0)	1 (0.1)	11 (1.5)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2-2 2021-09-22 16:57

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-shiftctc.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Bilirubin (umol/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	519 (98.1)	471 (90.8)	27 (5.2)	16 (3.1)	4 (0.8)	0	1 (0.2)
		Grade 1	8 (1.5)	5 (62.5)	3 (37.5)	0	0	0	0
		Grade 2	2 (0.4)	0	2 (100)	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	476 (90.0)	32 (6.0)	16 (3.0)	4 (0.8)	0	1 (0.2)
	BSC/BSoC only (N=205)	Grade 0	202 (98.5)	168 (83.2)	11 (5.4)	15 (7.4)	1 (0.5)	0	7 (3.5)
		Grade 1	2 (1.0)	1 (50.0)	0	1 (50.0)	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	1 (0.5)	1 (100)	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	170 (82.9)	11 (5.4)	16 (7.8)	1 (0.5)	0	7 (3.4)
Overall (N=734)	Overall (N=734)	Grade 0	721 (98.2)	639 (88.6)	38 (5.3)	31 (4.3)	5 (0.7)	0	8 (1.1)
		Grade 1	10 (1.4)	6 (60.0)	3 (30.0)	1 (10.0)	0	0	0
		Grade 2	2 (0.3)	0	2 (100)	0	0	0	0
		Grade 3	1 (0.1)	1 (100)	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	646 (88.0)	43 (5.9)	32 (4.4)	5 (0.7)	0	8 (1.1)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Calcium (mmol/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	483 (91.3)	293 (60.7)	139 (28.8)	40 (8.3)	5 (1.0)	5 (1.0)	1 (0.2)
		Grade 1	37 (7.0)	2 (5.4)	18 (48.6)	15 (40.5)	2 (5.4)	0	0
		Grade 2	6 (1.1)	1 (16.7)	0	4 (66.7)	0	1 (16.7)	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	3 (0.6)	1 (33.3)	2 (66.7)	0	0	0	0
		Total	529 (100)	297 (56.1)	159 (30.1)	59 (11.2)	7 (1.3)	6 (1.1)	1 (0.2)
	BSC/BSoC only (N=205)	Grade 0	186 (90.7)	131 (70.4)	36 (19.4)	10 (5.4)	2 (1.1)	2 (1.1)	5 (2.7)
		Grade 1	16 (7.8)	2 (12.5)	8 (50.0)	3 (18.8)	1 (6.3)	0	2 (12.5)
		Grade 2	3 (1.5)	0	2 (66.7)	0	1 (33.3)	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	133 (64.9)	46 (22.4)	13 (6.3)	4 (2.0)	2 (1.0)	7 (3.4)
Overall (N=734)	Overall (N=734)	Grade 0	669 (91.1)	424 (63.4)	175 (26.2)	50 (7.5)	7 (1.0)	7 (1.0)	6 (0.9)
		Grade 1	53 (7.2)	4 (7.5)	26 (49.1)	18 (34.0)	3 (5.7)	0	2 (3.8)
		Grade 2	9 (1.2)	1 (11.1)	2 (22.2)	4 (44.4)	1 (11.1)	1 (11.1)	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	3 (0.4)	1 (33.3)	2 (66.7)	0	0	0	0
		Total	734 (100)	430 (58.6)	205 (27.9)	72 (9.8)	11 (1.5)	8 (1.1)	8 (1.1)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2 2021-09-22 16:57

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-shiftctc.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Calcium (mmol/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	515 (97.4)	464 (90.1)	47 (9.1)	0	0	3 (0.6)	1 (0.2)
		Grade 1	11 (2.1)	4 (36.4)	6 (54.5)	1 (9.1)	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	3 (0.6)	3 (100)	0	0	0	0	0
		Total	529 (100)	471 (89.0)	53 (10.0)	1 (0.2)	0	3 (0.6)	1 (0.2)
	BSC/BSoC only (N=205)	Grade 0	201 (98.0)	182 (90.5)	12 (6.0)	0	0	0	7 (3.5)
		Grade 1	4 (2.0)	2 (50.0)	1 (25.0)	0	1 (25.0)	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	184 (89.8)	13 (6.3)	0	1 (0.5)	0	7 (3.4)
Overall (N=734)	Overall (N=734)	Grade 0	716 (97.5)	646 (90.2)	59 (8.2)	0	0	3 (0.4)	8 (1.1)
		Grade 1	15 (2.0)	6 (40.0)	7 (46.7)	1 (6.7)	1 (6.7)	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	3 (0.4)	3 (100)	0	0	0	0	0
		Total	734 (100)	655 (89.2)	66 (9.0)	1 (0.1)	1 (0.1)	3 (0.4)	8 (1.1)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Creatinine (umol/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	479 (90.5)	364 (76.0)	59 (12.3)	52 (10.9)	4 (0.8)	0	0
		Grade 1	46 (8.7)	3 (6.5)	28 (60.9)	15 (32.6)	0	0	0
		Grade 2	4 (0.8)	0	0	3 (75.0)	1 (25.0)	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	367 (69.4)	87 (16.4)	70 (13.2)	5 (0.9)	0	0
	BSC/BSoC only (N=205)	Grade 0	178 (86.8)	148 (83.1)	12 (6.7)	12 (6.7)	0	0	6 (3.4)
		Grade 1	25 (12.2)	3 (12.0)	17 (68.0)	3 (12.0)	1 (4.0)	0	1 (4.0)
		Grade 2	2 (1.0)	0	2 (100)	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	151 (73.7)	31 (15.1)	15 (7.3)	1 (0.5)	0	7 (3.4)
Overall (N=734)	Overall (N=734)	Grade 0	657 (89.5)	512 (77.9)	71 (10.8)	64 (9.7)	4 (0.6)	0	6 (0.9)
		Grade 1	71 (9.7)	6 (8.5)	45 (63.4)	18 (25.4)	1 (1.4)	0	1 (1.4)
		Grade 2	6 (0.8)	0	2 (33.3)	3 (50.0)	1 (16.7)	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	518 (70.6)	118 (16.1)	85 (11.6)	6 (0.8)	0	7 (1.0)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Glucose (mmol/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	525 (99.2)	478 (91.0)	46 (8.8)	1 (0.2)	0	0	0
		Grade 1	3 (0.6)	0	3 (100)	0	0	0	0
		Grade 2	1 (0.2)	0	1 (100)	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	478 (90.4)	50 (9.5)	1 (0.2)	0	0	0
	BSC/BSoC only (N=205)	Grade 0	202 (98.5)	184 (91.1)	9 (4.5)	1 (0.5)	0	0	8 (4.0)
		Grade 1	3 (1.5)	2 (66.7)	1 (33.3)	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	186 (90.7)	10 (4.9)	1 (0.5)	0	0	8 (3.9)
Overall (N=734)	Overall (N=734)	Grade 0	727 (99.0)	662 (91.1)	55 (7.6)	2 (0.3)	0	0	8 (1.1)
		Grade 1	6 (0.8)	2 (33.3)	4 (66.7)	0	0	0	0
		Grade 2	1 (0.1)	0	1 (100)	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	664 (90.5)	60 (8.2)	2 (0.3)	0	0	8 (1.1)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Potassium (mmol/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	516 (97.5)	436 (84.5)	75 (14.5)	0	5 (1.0)	0	0
		Grade 1	12 (2.3)	3 (25.0)	8 (66.7)	0	1 (8.3)	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	1 (0.2)	0	0	0	0	1 (100)	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	439 (83.0)	83 (15.7)	0	6 (1.1)	1 (0.2)	0
	BSC/BSoC only (N=205)	Grade 0	197 (96.1)	161 (81.7)	28 (14.2)	0	0	0	8 (4.1)
		Grade 1	8 (3.9)	2 (25.0)	6 (75.0)	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	163 (79.5)	34 (16.6)	0	0	0	8 (3.9)
Overall (N=734)	Overall (N=734)	Grade 0	713 (97.1)	597 (83.7)	103 (14.4)	0	5 (0.7)	0	8 (1.1)
		Grade 1	20 (2.7)	5 (25.0)	14 (70.0)	0	1 (5.0)	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	1 (0.1)	0	0	0	0	1 (100)	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	602 (82.0)	117 (15.9)	0	6 (0.8)	1 (0.1)	8 (1.1)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Potassium (mmol/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	516 (97.5)	391 (75.8)	101 (19.6)	22 (4.3)	1 (0.2)	1 (0.2)	0
		Grade 1	12 (2.3)	2 (16.7)	7 (58.3)	3 (25.0)	0	0	0
		Grade 2	1 (0.2)	0	0	0	1 (100)	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	393 (74.3)	108 (20.4)	25 (4.7)	2 (0.4)	1 (0.2)	0
	BSC/BSoC only (N=205)	Grade 0	196 (95.6)	154 (78.6)	28 (14.3)	6 (3.1)	1 (0.5)	0	7 (3.6)
		Grade 1	7 (3.4)	3 (42.9)	3 (42.9)	0	0	0	1 (14.3)
		Grade 2	2 (1.0)	1 (50.0)	1 (50.0)	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	158 (77.1)	32 (15.6)	6 (2.9)	1 (0.5)	0	8 (3.9)
Overall (N=734)	Overall (N=734)	Grade 0	712 (97.0)	545 (76.5)	129 (18.1)	28 (3.9)	2 (0.3)	1 (0.1)	7 (1.0)
		Grade 1	19 (2.6)	5 (26.3)	10 (52.6)	3 (15.8)	0	0	1 (5.3)
		Grade 2	3 (0.4)	1 (33.3)	1 (33.3)	0	1 (33.3)	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	551 (75.1)	140 (19.1)	31 (4.2)	3 (0.4)	1 (0.1)	8 (1.1)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Lactate dehydrogenase (IU/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	303 (57.3)	162 (53.5)	140 (46.2)	0	0	0	1 (0.3)
		Grade 1	226 (42.7)	10 (4.4)	215 (95.1)	0	0	0	1 (0.4)
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	172 (32.5)	355 (67.1)	0	0	0	2 (0.4)
	BSC/BSoC only (N=205)	Grade 0	112 (54.6)	64 (57.1)	44 (39.3)	0	0	0	4 (3.6)
		Grade 1	93 (45.4)	6 (6.5)	79 (84.9)	0	0	0	8 (8.6)
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	70 (34.1)	123 (60.0)	0	0	0	12 (5.9)
Overall (N=734)	Overall (N=734)	Grade 0	415 (56.5)	226 (54.5)	184 (44.3)	0	0	0	5 (1.2)
		Grade 1	319 (43.5)	16 (5.0)	294 (92.2)	0	0	0	9 (2.8)
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	242 (33.0)	478 (65.1)	0	0	0	14 (1.9)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Sodium (mmol/L) Low	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	495 (93.6)	322 (65.1)	152 (30.7)	19 (3.8)	2 (0.4)	0	0
		Grade 1	32 (6.0)	2 (6.3)	24 (75.0)	5 (15.6)	1 (3.1)	0	0
		Grade 2	1 (0.2)	0	1 (100)	0	0	0	0
		Grade 3	1 (0.2)	0	0	0	1 (100)	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
	BSC/BSoC only (N=205)	Total	529 (100)	324 (61.2)	177 (33.5)	24 (4.5)	4 (0.8)	0	0
		Grade 0	192 (93.7)	141 (73.4)	37 (19.3)	5 (2.6)	1 (0.5)	1 (0.5)	7 (3.6)
		Grade 1	10 (4.9)	6 (60.0)	3 (30.0)	1 (10.0)	0	0	0
		Grade 2	3 (1.5)	0	0	3 (100)	0	0	0
Overall (N=734)	Overall (N=734)	Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	147 (71.7)	40 (19.5)	9 (4.4)	1 (0.5)	1 (0.5)	7 (3.4)
		Grade 0	687 (93.6)	463 (67.4)	189 (27.5)	24 (3.5)	3 (0.4)	1 (0.1)	7 (1.0)
		Grade 1	42 (5.7)	8 (19.0)	27 (64.3)	6 (14.3)	1 (2.4)	0	0
		Grade 2	4 (0.5)	0	1 (25.0)	3 (75.0)	0	0	0
	Overall (N=734)	Grade 3	1 (0.1)	0	0	0	1 (100)	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	471 (64.2)	217 (29.6)	33 (4.5)	5 (0.7)	1 (0.1)	7 (1.0)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-2 Chemistry shift table during randomized treatment based on CTC grades (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Sodium (mmol/L) High	Lu-PSMA-617+ BSC/BSoC (N=529)	Grade 0	520 (98.3)	462 (88.8)	55 (10.6)	3 (0.6)	0	0	0
		Grade 1	8 (1.5)	6 (75.0)	2 (25.0)	0	0	0	0
		Grade 2	1 (0.2)	1 (100)	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	529 (100)	469 (88.7)	57 (10.8)	3 (0.6)	0	0	0
	BSC/BSoC only (N=205)	Grade 0	200 (97.6)	184 (92.0)	9 (4.5)	0	0	0	7 (3.5)
		Grade 1	5 (2.4)	2 (40.0)	2 (40.0)	1 (20.0)	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	205 (100)	186 (90.7)	11 (5.4)	1 (0.5)	0	0	7 (3.4)
Overall (N=734)	Overall (N=734)	Grade 0	720 (98.1)	646 (89.7)	64 (8.9)	3 (0.4)	0	0	7 (1.0)
		Grade 1	13 (1.8)	8 (61.5)	4 (30.8)	1 (7.7)	0	0	0
		Grade 2	1 (0.1)	1 (100)	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	734 (100)	655 (89.2)	68 (9.3)	4 (0.5)	0	0	7 (1.0)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2-2 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 3-2-2-2s Chemistry shift table during study treatment based on CTC grades (Sub-study safety analysis set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Albumin (g/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	27 (90.0)	23 (85.2)	3 (11.1)	1 (3.7)	0	0	0
		Grade 1	3 (10.0)	1 (33.3)	1 (33.3)	0	0	0	1 (33.3)
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	24 (80.0)	4 (13.3)	1 (3.3)	0	0	1 (3.3)
Alkaline phosphatase (IU/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	21 (70.0)	11 (52.4)	7 (33.3)	2 (9.5)	0	0	1 (4.8)
		Grade 1	5 (16.7)	4 (80.0)	0	1 (20.0)	0	0	0
		Grade 2	2 (6.7)	1 (50.0)	0	1 (50.0)	0	0	0
		Grade 3	2 (6.7)	2 (100)	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	18 (60.0)	7 (23.3)	4 (13.3)	0	0	1 (3.3)
Alanine aminotransferase (IU/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	29 (96.7)	26 (89.7)	0	2 (6.9)	0	0	1 (3.4)
		Grade 1	1 (3.3)	1 (100)	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	27 (90.0)	0	2 (6.7)	0	0	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-2-2s 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-2-2s Chemistry shift table during study treatment based on CTC grades (Sub-study safety analysis set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Aspartate aminotransferase (IU/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	25 (83.3)	16 (64.0)	8 (32.0)	0	0	0	1 (4.0)
		Grade 1	4 (13.3)	1 (25.0)	2 (50.0)	1 (25.0)	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	1 (3.3)	1 (100)	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
Bilirubin (umol/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Total	30 (100)	18 (60.0)	10 (33.3)	1 (3.3)	0	0	1 (3.3)
		Grade 0	29 (96.7)	27 (93.1)	1 (3.4)	0	0	0	1 (3.4)
		Grade 1	1 (3.3)	0	1 (100)	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
Calcium (mmol/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Missing	0	0	0	0	0	0	0
		Total	30 (100)	27 (90.0)	2 (6.7)	0	0	0	1 (3.3)
		Grade 0	27 (90.0)	19 (70.4)	6 (22.2)	2 (7.4)	0	0	0
		Grade 1	1 (3.3)	0	0	0	0	0	1 (100)
		Grade 2	2 (6.7)	0	0	2 (100)	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	19 (63.3)	6 (20.0)	4 (13.3)	0	0	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-2-2s 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 3-2-2-2s Chemistry shift table during study treatment based on CTC grades (Sub-study safety analysis set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Calcium (mmol/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	30 (100)	29 (96.7)	0	0	0	0	1 (3.3)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	29 (96.7)	0	0	0	0	1 (3.3)
Creatinine (umol/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	29 (96.7)	22 (75.9)	2 (6.9)	4 (13.8)	0	0	1 (3.4)
		Grade 1	1 (3.3)	1 (100)	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	23 (76.7)	2 (6.7)	4 (13.3)	0	0	1 (3.3)
Glucose (mmol/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	29 (96.7)	20 (69.0)	5 (17.2)	2 (6.9)	0	1 (3.4)	1 (3.4)
		Grade 1	1 (3.3)	0	1 (100)	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	20 (66.7)	6 (20.0)	2 (6.7)	0	1 (3.3)	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-2-2s 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-2-2s Chemistry shift table during study treatment based on CTC grades (Sub-study safety analysis set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Potassium (mmol/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	30 (100)	27 (90.0)	2 (6.7)	0	0	0	1 (3.3)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	27 (90.0)	2 (6.7)	0	0	0	1 (3.3)
Potassium (mmol/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	25 (83.3)	16 (64.0)	7 (28.0)	0	1 (4.0)	0	1 (4.0)
		Grade 1	3 (10.0)	1 (33.3)	1 (33.3)	1 (33.3)	0	0	0
		Grade 2	2 (6.7)	1 (50.0)	0	0	1 (50.0)	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	18 (60.0)	8 (26.7)	1 (3.3)	2 (6.7)	0	1 (3.3)
Lactate dehydrogenase (IU/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	12 (40.0)	3 (25.0)	9 (75.0)	0	0	0	0
		Grade 1	18 (60.0)	1 (5.6)	16 (88.9)	0	0	0	1 (5.6)
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	4 (13.3)	25 (83.3)	0	0	0	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-2-2s 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-2-2s Chemistry shift table during study treatment based on CTC grades (Sub-study safety analysis set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value					
		Grade	n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)
Sodium (mmol/L) Low	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	29 (96.7)	25 (86.2)	3 (10.3)	0	0	0	1 (3.4)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	1 (3.3)	1 (100)	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	26 (86.7)	3 (10.0)	0	0	0	1 (3.3)
Sodium (mmol/L) High	Lu-PSMA-617+ BSC/BSoC (N=30)	Grade 0	30 (100)	28 (93.3)	1 (3.3)	0	0	0	1 (3.3)
		Grade 1	0	0	0	0	0	0	0
		Grade 2	0	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0	0
		Missing	0	0	0	0	0	0	0
		Total	30 (100)	28 (93.3)	1 (3.3)	0	0	0	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Grades based on CTCAE version 5.0.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-2-2s 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

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Advanced Accelerator Applications, a Novartis Company

177Lu-PSMA-617 SCS update

Final Version

Table 3-2-2-3 Worst post-baseline chemistry abnormalities during long-term follow up based on CTC grades (FAS safety set)

	Lu-PSMA-617+BSC/BSoC (N=529)		BSC/BSoC only (N=205)		Overall (N=734)	
	All Grades n (%)	Grades 3/4 n (%)	All Grades n (%)	Grades 3/4 n (%)	All Grades n (%)	Grades 3/4 n (%)
Alanine aminotransferase (IU/L) - Increased	25 (4.7)	1 (0.2)	12 (5.9)	0	37 (5.0)	1 (0.1)
Albumin (g/L) - Hypoalbuminemia	51 (9.6)	1 (0.2)	30 (14.6)	0	81 (11.0)	1 (0.1)
Alkaline phosphatase (IU/L) - Increased	62 (11.7)	7 (1.3)	31 (15.1)	4 (2.0)	93 (12.7)	11 (1.5)
Aspartate aminotransferase (IU/L) - Increased	44 (8.3)	2 (0.4)	21 (10.2)	1 (0.5)	65 (8.9)	3 (0.4)
Bilirubin (umol/L) - Increased	7 (1.3)	0	9 (4.4)	1 (0.5)	16 (2.2)	1 (0.1)
Calcium (mmol/L) - Hypercalcemia	0	0	5 (2.4)	0	5 (0.7)	0
Calcium (mmol/L) - Hypocalcemia	48 (9.1)	5 (0.9)	27 (13.2)	1 (0.5)	75 (10.2)	6 (0.8)
Creatinine (umol/L) - Increased	42 (7.9)	2 (0.4)	19 (9.3)	0	61 (8.3)	2 (0.3)
Glucose (mmol/L) - Hypoglycemia	2 (0.4)	0	2 (1.0)	0	4 (0.5)	0
Lactate dehydrogenase (IU/L) - Increased	63 (11.9)	0	34 (16.6)	0	97 (13.2)	0
Potassium (mmol/L) - Hyperkalemia	12 (2.3)	0	10 (4.9)	1 (0.5)	22 (3.0)	1 (0.1)
Potassium (mmol/L) - Hypokalemia	13 (2.5)	0	6 (2.9)	1 (0.5)	19 (2.6)	1 (0.1)
Sodium (mmol/L) - Hypernatremia	2 (0.4)	0	2 (1.0)	0	4 (0.5)	0
Sodium (mmol/L) - Hyponatremia	35 (6.6)	0	17 (8.3)	1 (0.5)	52 (7.1)	1 (0.1)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

All grades' represents patients with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Output ID: T-3-2-2-3 2021-09-22 17:00

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 3-2-2-4 Categorical analysis of hepatic laboratory values during randomized treatment (FAS safety set)

	Lu-PSMA-617+ BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Worst post-baseline values			
ALT >3x ULN	13 (2.5)	5 (2.4)	18 (2.5)
ALT >5x ULN	2 (0.4)	3 (1.5)	5 (0.7)
ALT >8x ULN	0	2 (1.0)	2 (0.3)
ALT >10x ULN	0	2 (1.0)	2 (0.3)
ALT >20x ULN	0	0	0
AST >3x ULN	37 (7.0)	12 (5.9)	49 (6.7)
AST >5x ULN	10 (1.9)	4 (2.0)	14 (1.9)
AST >8x ULN	2 (0.4)	3 (1.5)	5 (0.7)
AST >10x ULN	2 (0.4)	1 (0.5)	3 (0.4)
AST >20x ULN	1 (0.2)	0	1 (0.1)
ALT or AST >3x ULN	43 (8.1)	15 (7.3)	58 (7.9)
ALT or AST >5x ULN	11 (2.1)	6 (2.9)	17 (2.3)
ALT or AST >8x ULN	2 (0.4)	4 (2.0)	6 (0.8)
ALT or AST >10x ULN	2 (0.4)	3 (1.5)	5 (0.7)
ALT or AST >20x ULN	1 (0.2)	0	1 (0.1)
Total bilirubin >2x ULN	5 (0.9)	3 (1.5)	8 (1.1)
Total bilirubin >3x ULN	3 (0.6)	0	3 (0.4)
Combined and concurrent values post-baseline			
ALT >3x ULN & BILI >2x ULN	2 (0.4)	1 (0.5)	3 (0.4)
AST >3x ULN & BILI >2x ULN	3 (0.6)	2 (1.0)	5 (0.7)
ALT or AST >3x ULN & BILI >2x ULN	3 (0.6)	3 (1.5)	6 (0.8)
ALT or AST >3x ULN & BILI >2x ULN & ALP >=2x ULN	3 (0.6)	3 (1.5)	6 (0.8)
ALT or AST >3x ULN & BILI >2x ULN & ALP <2x ULN	0	0	0

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Concurrent measurements are those occurring in the same assessment sample.

Output ID: T-3-2-2-4 2021-09-22 16:56

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Source data: adsl.xpt, adlb.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 3-2-2-4s Categorical analysis of hepatic laboratory values during study treatment (Sub-study safety analysis set)

	Lu-PSMA-617+ BSC/BSoC (N=30) n (%)
Worst post-baseline values	
ALT >3x ULN	2 (6.7)
ALT >5x ULN	0
ALT >8x ULN	0
ALT >10x ULN	0
ALT >20x ULN	0
AST >3x ULN	1 (3.3)
AST >5x ULN	1 (3.3)
AST >8x ULN	1 (3.3)
AST >10x ULN	0
AST >20x ULN	0
ALT or AST >3x ULN	2 (6.7)
ALT or AST >5x ULN	1 (3.3)
ALT or AST >8x ULN	1 (3.3)
ALT or AST >10x ULN	0
ALT or AST >20x ULN	0
Total bilirubin >2x ULN	0
Total bilirubin >3x ULN	0
Combined and concurrent values post-baseline	
ALT >3x ULN & BILI >2x ULN	0
AST >3x ULN & BILI >2x ULN	0
ALT or AST >3x ULN & BILI >2x ULN	0
ALT or AST >3x ULN & BILI >2x ULN & ALP >=2x ULN	0
ALT or AST >3x ULN & BILI >2x ULN & ALP <2x ULN	0

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Concurrent measurements are those occurring in the same assessment sample.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-2-4s 2021-09-22 16:56

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Source data: adsl.xpt, adlb.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update
Table 3-2-2-5 Categorical analysis of hepatic laboratory values during long-term follow up (FAS safety set)

	Lu-PSMA-617+ BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Worst post-baseline values			
ALT >3x ULN	3 (0.6)	1 (0.5)	4 (0.5)
ALT >5x ULN	1 (0.2)	0	1 (0.1)
ALT >8x ULN	0	0	0
ALT >10x ULN	0	0	0
ALT >20x ULN	0	0	0
AST >3x ULN	11 (2.1)	5 (2.4)	16 (2.2)
AST >5x ULN	3 (0.6)	2 (1.0)	5 (0.7)
AST >8x ULN	1 (0.2)	0	1 (0.1)
AST >10x ULN	1 (0.2)	0	1 (0.1)
AST >20x ULN	0	0	0
ALT or AST >3x ULN	11 (2.1)	5 (2.4)	16 (2.2)
ALT or AST >5x ULN	4 (0.8)	2 (1.0)	6 (0.8)
ALT or AST >8x ULN	1 (0.2)	0	1 (0.1)
ALT or AST >10x ULN	1 (0.2)	0	1 (0.1)
ALT or AST >20x ULN	0	0	0
Total bilirubin >2x ULN	0	1 (0.5)	1 (0.1)
Total bilirubin >3x ULN	0	1 (0.5)	1 (0.1)
Combined and concurrent values post-baseline			
ALT >3x ULN & BILI >2x ULN	0	0	0
AST >3x ULN & BILI >2x ULN	0	1 (0.5)	1 (0.1)
ALT or AST >3x ULN & BILI >2x ULN	0	1 (0.5)	1 (0.1)
ALT or AST >3x ULN & BILI >2x ULN & ALP >=2x ULN	0	1 (0.5)	1 (0.1)
ALT or AST >3x ULN & BILI >2x ULN & ALP <2x ULN	0	0	0

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Concurrent measurements are those occurring in the same assessment sample.

Output ID: T-3-2-2-5 2021-09-22 16:56

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Source data: adsl.xpt, adlb.xpt

Data Cutoff Date: 28JUN2021

Table 3-2-2-6 Serum testosterone shift table during randomized treatment based on normal ranges (FAS safety set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value			
		n (%)	Normal n (%)	High only n (%)	Low only n (%)	High & low n (%)	Missing n (%)
Testosterone (nmol/L)	Lu-PSMA-617+ BSC/BSoC (N=529)	Normal 1 (0.2)	0	0	1 (100)	0	0
	High 0	0	0	0	0	0	0
	Low 526 (99.4)	0	1 (0.2)	510 (97.0)	1 (0.2)	14 (2.7)	
	Missing 2 (0.4)	0	0	1 (50.0)	0	1 (50.0)	
	Total 529 (100)	0	1 (0.2)	512 (96.8)	1 (0.2)	15 (2.8)	
BSC/BSoC only (N=205)	Normal 0	0	0	0	0	0	0
	High 0	0	0	0	0	0	0
	Low 203 (99.0)	0	0	165 (81.3)	0	38 (18.7)	
	Missing 2 (1.0)	0	0	0	0	2 (100)	
	Total 205 (100)	0	0	165 (80.5)	0	40 (19.5)	
Overall (N=734)	Normal 1 (0.1)	0	0	1 (100)	0	0	0
	High 0	0	0	0	0	0	0
	Low 729 (99.3)	0	1 (0.1)	675 (92.6)	1 (0.1)	52 (7.1)	
	Missing 4 (0.5)	0	0	1 (25.0)	0	3 (75.0)	
	Total 734 (100)	0	1 (0.1)	677 (92.2)	1 (0.1)	55 (7.5)	

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Output ID: T-3-2-2-6 2021-09-22 16:57

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-shiftl.sas

Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 SCS update

Table 3-2-2-6s Serum testosterone shift table during study treatment based on normal ranges (Sub-study safety analysis set)

Parameter (unit)	Treatment	Baseline		Worst post-baseline value				Missing n (%)
		n (%)	Normal n (%)	High only n (%)	Low only n (%)	High & low n (%)		
Testosterone (nmol/L)	Lu-PSMA-617+ BSC/BSoC (N=30)	Normal	0	0	0	0	0	0
		High	0	0	0	0	0	0
		Low	30 (100)	0	0	29 (96.7)	0	1 (3.3)
		Missing	0	0	0	0	0	0
		Total	30 (100)	0	0	29 (96.7)	0	1 (3.3)

Results given as xx (xx.x) where xx=number of patients, (xx.x)=percentage

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-3-2-2-6s 2021-09-22 16:57

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Source data: adlb.xpt, adsl.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 4-1-1 Notable vital signs during randomized treatment (FAS safety set)

Vital sign Category	Lu-PSMA-617+BSC/BSoC C (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Systolic blood pressure			
>=180 mmHg and increase >=20 mmHg from baseline	32 (6.0)	1 (0.5)	33 (4.5)
<=90 mmHg and decrease >=20 mmHg from baseline	5 (0.9)	3 (1.5)	8 (1.1)
Diastolic blood pressure			
>=105 mmHg and increase >=15 mmHg from baseline	14 (2.6)	2 (1.0)	16 (2.2)
<=50 mmHg and decrease >=15 mmHg from baseline	20 (3.8)	3 (1.5)	23 (3.1)
Pulse rate			
>=100 bpm and increase >25% from baseline	50 (9.5)	8 (3.9)	58 (7.9)
<=50 bpm and decrease >25% from baseline	16 (3.0)	1 (0.5)	17 (2.3)
Weight			
Increase >10% from baseline	26 (4.9)	3 (1.5)	29 (4.0)
Decrease >10% from baseline	69 (13.0)	13 (6.3)	82 (11.2)

Output ID: T-4-1-1-2021-09-22 17:09

...BIOMETRY\PROJECTS\PSMA617\VISION\SAFETY_UPDATE_90DAYS\PRODUCTION\TLF\PGM\lt-vs-crit.sas

Source data: adsl.xpt, advs.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 SCS update

Final Version

Table 4-1-1s Notable vital signs during study treatment (Sub-study safety analysis set)

Vital sign Category	Lu-PSMA-617+BSC/BSoC (N=30) n (%)
Systolic blood pressure >=180 mmHg and increase >=20 mmHg from baseline	2 (6.7)
<=90 mmHg and decrease >=20 mmHg from baseline	1 (3.3)
Diastolic blood pressure >=105 mmHg and increase >=15 mmHg from baseline	1 (3.3)
<=50 mmHg and decrease >=15 mmHg from baseline	3 (10.0)
Pulse rate >=100 bpm and increase >25% from baseline	4 (13.3)
<=50 bpm and decrease >25% from baseline	1 (3.3)
Weight Increase >10% from baseline	0
Decrease >10% from baseline	1 (3.3)

Study treatment refers to 177Lu-PSMA-617+BSC/BSoC

Output ID: T-4-1-1s 2021-09-22 17:09

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-vs-crit.sas

Source data: adsl.xpt, advs.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 ADR update

Table A2-1 Adverse drug reactions - randomized treatment-emergent adverse events regardless of study drug relationship, by primary system organ class and ADR group (FAS safety set)

Risk System Organ Class Adverse Drug Reaction	Lu-PSMA-617 +BSC/BSoc (N=529)				BSC/BSoC only (N=205)			
	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3
Blood and lymphatic system disorders								
ADR Anaemia	168 (31.8)	Very Common	68 (12.9)	Very Common	27 (13.2)	Very Common	10 (4.9)	Common
ADR Leukopenia	83 (15.7)	Very Common	22 (4.2)	Common	4 (2.0)	Common	1 (0.5)	Uncommon
ADR Lymphopenia	75 (14.2)	Very Common	41 (7.8)	Common	8 (3.9)	Common	1 (0.5)	Uncommon
ADR Pancytopenia	9 (1.7)*	Common	7 (1.3)*	Common	0		0	
ADR Thrombocytopenia	91 (17.2)	Very Common	42 (7.9)	Common	9 (4.4)	Common	2 (1.0)	Uncommon
Ear and labyrinth disorders								
ADR Vertigo	11 (2.1)	Common	0		0		0	
Eye disorders								
ADR Dry eye	16 (3.0)	Common	0		2 (1.0)	Uncommon	0	
Gastrointestinal disorders								
ADR Abdominal pain	61 (11.5)	Very Common	7 (1.3)	Common	13 (6.3)	Common	1 (0.5)	Uncommon
ADR Constipation	107 (20.2)	Very Common	6 (1.1)	Common	23 (11.2)	Very Common	1 (0.5)	Uncommon
ADR Diarrhea	101 (19.1)	Very Common	4 (0.8)	Uncommon	6 (2.9)	Common	1 (0.5)	Uncommon
ADR Dry mouth	208 (39.3)	Very Common	0		1 (0.5)	Uncommon	0	
ADR Nausea	188 (35.5)	Very Common	7 (1.3)	Common	34 (16.6)	Very Common	1 (0.5)	Uncommon
ADR Vomiting	101 (19.1)	Very Common	5 (0.9)	Uncommon	13 (6.3)	Common	1 (0.5)	Uncommon
General disorders and administration site conditions								
ADR Decreased appetite	113 (21.4)	Very Common	10 (1.9)	Common	30 (14.6)	Very Common	1 (0.5)	Uncommon
ADR Fatigue	228 (43.1)	Very Common	31 (5.9)	Common	47 (22.9)	Very Common	3 (1.5)	Common
ADR Oedema peripheral	52 (9.8)	Common	2 (0.4)	Uncommon	14 (6.8)	Common	1 (0.5)	Uncommon
ADR Pyrexia	37 (7.0)	Common	2 (0.4)	Uncommon	7 (3.4)	Common	0	
ADR Weight decreased	58 (11.0)	Very Common	2 (0.4)	Uncommon	20 (9.8)	Common	1 (0.5)	Uncommon
Nervous system disorders								

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177Lu-PSMA-617 ADR update

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Risk System Organ Class Adverse Drug Reaction	Lu-PSMA-617 +BSC/BSoc (N=529)				BSC/BSoc only (N=205)			
	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3
ADR Dizziness	44 (8.3)	Common	5 (0.9)	Uncommon	9 (4.4)	Common	0	
ADR Dysgeusia	37 (7.0)	Common	0		3 (1.5)	Common	0	
ADR Headache	37 (7.0)	Common	4 (0.8)	Uncommon	4 (2.0)	Common	0	
Renal and urinary disorders								
ADR Acute kidney injury	45 (8.5)	Common	17 (3.2)	Common	12 (5.9)	Common	6 (2.9)	Common
ADR Urinary tract infection	62 (11.7)	Very Common	20 (3.8)	Common	2 (1.0)	Uncommon	1 (0.5)	Uncommon

* ADRs or PTs for which at least one Grade 5 was observed

Numbers (n) represent counts of subjects.

A subject with multiple severity grades for events contributing to an ADR or PT is only counted under the maximum grade.

Frequency category is based on the following convention: very common (>=1/10); common (>=1/100 to <1/10); uncommon (>=1/1,000 to <1/100); rare (>=1/10,000 to <1/1,000); very rare (<1/10,000).

MedDRA version 24.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-A2-1 2021-09-22 17:05

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-teae-soc-adr.sas

Source data: adsl.xpt, adadr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 ADR update

Table A2-2 Adverse drug reactions - randomized treatment-emergent adverse events regardless of study drug relationship, by ADR group and preferred term (FAS safety set)

Adverse Drug Reaction Preferred Term	Lu-PSMA-617 +BSC/BSoc (N=529)				BSC/BSoc only (N=205)			
	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3
ADR Abdominal pain	61 (11.5)	Very Common	7 (1.3)	Common	13 (6.3)	Common	1 (0.5)	Uncommon
Abdominal discomfort	7 (1.3)	Common	0		1 (0.5)	Uncommon	0	
Abdominal pain	33 (6.2)	Common	5 (0.9)	Uncommon	7 (3.4)	Common	1 (0.5)	Uncommon
Abdominal pain lower	5 (0.9)	Uncommon	1 (0.2)	Uncommon	2 (1.0)	Uncommon	0	
Abdominal pain upper	17 (3.2)	Common	1 (0.2)	Uncommon	4 (2.0)	Common	0	
Abdominal tenderness	1 (0.2)	Uncommon	0		0		0	
Gastrointestinal pain	1 (0.2)	Uncommon	0		0		0	
ADR Acute kidney injury	45 (8.5)	Common	17 (3.2)	Common	12 (5.9)	Common	6 (2.9)	Common
Acute kidney injury	19 (3.6)	Common	16 (3.0)	Common	8 (3.9)	Common	5 (2.4)	Common
Blood creatinine increased	28 (5.3)	Common	1 (0.2)	Uncommon	5 (2.4)	Common	1 (0.5)	Uncommon
Blood urea increased	1 (0.2)	Uncommon	0		0		0	
Renal failure	1 (0.2)	Uncommon	0		0		0	
ADR Anaemia	168 (31.8)	Very Common	68 (12.9)	Very Common	27 (13.2)	Very Common	10 (4.9)	Common
Anaemia	168 (31.8)	Very Common	68 (12.9)	Very Common	27 (13.2)	Very Common	10 (4.9)	Common
ADR Constipation	107 (20.2)	Very Common	6 (1.1)	Common	23 (11.2)	Very Common	1 (0.5)	Uncommon
Constipation	107 (20.2)	Very Common	6 (1.1)	Common	23 (11.2)	Very Common	1 (0.5)	Uncommon
ADR Decreased appetite	113 (21.4)	Very Common	10 (1.9)	Common	30 (14.6)	Very Common	1 (0.5)	Uncommon
Decreased appetite	113 (21.4)	Very Common	10 (1.9)	Common	30 (14.6)	Very Common	1 (0.5)	Uncommon
ADR Diarrhea	101 (19.1)	Very Common	4 (0.8)	Uncommon	6 (2.9)	Common	1 (0.5)	Uncommon
Diarrhoea	101 (19.1)	Very Common	4 (0.8)	Uncommon	6 (2.9)	Common	1 (0.5)	Uncommon
ADR Dizziness	44 (8.3)	Common	5 (0.9)	Uncommon	9 (4.4)	Common	0	
Dizziness	44 (8.3)	Common	5 (0.9)	Uncommon	9 (4.4)	Common	0	
ADR Dry eye	16 (3.0)	Common	0		2 (1.0)	Uncommon	0	

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177Lu-PSMA-617 ADR update

Final Version

Adverse Drug Reaction Preferred Term	Lu-PSMA-617 +BSC/BSoc (N=529)				BSC/BSoc only (N=205)			
	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3
Dry eye	16 (3.0)	Common	0		2 (1.0)	Uncommon	0	
ADR Dry mouth	208 (39.3)	Very Common	0		1 (0.5)	Uncommon	0	
Aptyalism	2 (0.4)	Uncommon	0		0		0	
Dry mouth	205 (38.8)	Very Common	0		1 (0.5)	Uncommon	0	
Dry throat	1 (0.2)	Uncommon	0		0		0	
ADR Dysgeusia	37 (7.0)	Common	0		3 (1.5)	Common	0	
Dysgeusia	24 (4.5)	Common	0		3 (1.5)	Common	0	
Taste disorder	13 (2.5)	Common	0		0		0	
ADR Fatigue	228 (43.1)	Very Common	31 (5.9)	Common	47 (22.9)	Very Common	3 (1.5)	Common
Fatigue	228 (43.1)	Very Common	31 (5.9)	Common	47 (22.9)	Very Common	3 (1.5)	Common
ADR Headache	37 (7.0)	Common	4 (0.8)	Uncommon	4 (2.0)	Common	0	
Headache	37 (7.0)	Common	4 (0.8)	Uncommon	4 (2.0)	Common	0	
ADR Leukopenia	83 (15.7)	Very Common	22 (4.2)	Common	4 (2.0)	Common	1 (0.5)	Uncommon
Leukopenia	66 (12.5)	Very Common	13 (2.5)	Common	4 (2.0)	Common	1 (0.5)	Uncommon
Neutropenia	45 (8.5)	Common	18 (3.4)	Common	3 (1.5)	Common	1 (0.5)	Uncommon
ADR Lymphopenia	75 (14.2)	Very Common	41 (7.8)	Common	8 (3.9)	Common	1 (0.5)	Uncommon
Lymphopenia	75 (14.2)	Very Common	41 (7.8)	Common	8 (3.9)	Common	1 (0.5)	Uncommon
ADR Nausea	188 (35.5)	Very Common	7 (1.3)	Common	34 (16.6)	Very Common	1 (0.5)	Uncommon
Nausea	188 (35.5)	Very Common	7 (1.3)	Common	34 (16.6)	Very Common	1 (0.5)	Uncommon
ADR Oedema peripheral	52 (9.8)	Common	2 (0.4)	Uncommon	14 (6.8)	Common	1 (0.5)	Uncommon
Fluid overload	0		0		1 (0.5)	Uncommon	1 (0.5)	Uncommon
Fluid retention	1 (0.2)	Uncommon	0		0		0	
Oedema peripheral	51 (9.6)	Common	2 (0.4)	Uncommon	13 (6.3)	Common	0	
ADR Pancytopenia	9 (1.7)*	Common	7 (1.3)*	Common	0		0	
Bicytopenia	1 (0.2)	Uncommon	1 (0.2)	Uncommon	0		0	

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177Lu-PSMA-617 ADR update

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Adverse Drug Reaction Preferred Term	Lu-PSMA-617 +BSC/BSoc (N=529)				BSC/BSoc only (N=205)			
	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3	All grades n (%)	Frequency category All grades	Grade >=3 n (%)	Frequency category Grade >=3
Pancytopenia	8 (1.5)*	Common	6 (1.1)*	Common	0		0	
ADR Pyrexia	37 (7.0)	Common	2 (0.4)	Uncommon	7 (3.4)	Common	0	
Pyrexia	37 (7.0)	Common	2 (0.4)	Uncommon	7 (3.4)	Common	0	
ADR Thrombocytopenia	91 (17.2)	Very Common	42 (7.9)	Common	9 (4.4)	Common	2 (1.0)	Uncommon
Thrombocytopenia	91 (17.2)	Very Common	42 (7.9)	Common	9 (4.4)	Common	2 (1.0)	Uncommon
ADR Urinary tract infection	62 (11.7)	Very Common	20 (3.8)	Common	2 (1.0)	Uncommon	1 (0.5)	Uncommon
Cystitis	6 (1.1)	Common	1 (0.2)	Uncommon	0		0	
Cystitis bacterial	1 (0.2)	Uncommon	0		0		0	
Urinary tract infection	59 (11.2)	Very Common	20 (3.8)	Common	2 (1.0)	Uncommon	1 (0.5)	Uncommon
ADR Vertigo	11 (2.1)	Common	0		0		0	
Vertigo	11 (2.1)	Common	0		0		0	
ADR Vomiting	101 (19.1)	Very Common	5 (0.9)	Uncommon	13 (6.3)	Common	1 (0.5)	Uncommon
Retching	1 (0.2)	Uncommon	0		0		0	
Vomiting	100 (18.9)	Very Common	5 (0.9)	Uncommon	13 (6.3)	Common	1 (0.5)	Uncommon
ADR Weight decreased	58 (11.0)	Very Common	2 (0.4)	Uncommon	20 (9.8)	Common	1 (0.5)	Uncommon
Weight decreased	58 (11.0)	Very Common	2 (0.4)	Uncommon	20 (9.8)	Common	1 (0.5)	Uncommon

* ADRs or PTs for which at least one Grade 5 was observed

Numbers (n) represent counts of subjects.

A subject with multiple severity grades for events contributing to an ADR or PT is only counted under the maximum grade.

Frequency category is based on the following convention: very common (>=1/10); common (>=1/100 to <1/10); uncommon (>=1/1,000 to <1/100); rare (>=1/10,000 to <1/1,000); very rare (<1/10,000).

MedDRA version 24.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: t-a2-2 2021-09-22 17:04

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Source data: adsl.xpt, adadr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 ADR update
Table A2-3 Time to first occurrence of adverse drug reaction (FAS safety set)

Adverse Drug Reaction	Lu-PSMA-617 +BSC/BSoc (N=529)	BSC/BSoc only (N=205)
ADR Abdominal pain		
Number of subjects with at least one event, n (%)	61 (11.5)	13 (6.3)
Time to first occurrence (weeks) ^a		
Median (Min-Max)	11.4 (0.1-107.1)	2.4 (0.1-11.9)
Q1-Q3	1.7-23.7	0.7-6.1
Time to first occurrence (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	468 (88.5)	192 (93.7)
Median [95% CI]	NE [NE, NE]	NE [NE, NE]
Q1-Q3	NE-NE	NE-NE
% Event probability estimate [95% CI]		
Week 4	3.4 [2.2, 5.4]	3.5 [1.7, 7.2]
Week 8	4.6 [3.1, 6.7]	5.2 [2.8, 9.4]
Week 12	6.1 [4.4, 8.6]	7.6 [4.4, 12.8]
Week 24	9.3 [7.0, 12.3]	7.6 [4.4, 12.8]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]		
% Event probability estimate [95% CI]		
Week 4	3.4 [2.1, 5.2]	3.4 [1.5, 6.6]
Week 8	4.5 [3.0, 6.6]	4.9 [2.5, 8.4]
Week 12	6.0 [4.2, 8.3]	6.3 [3.5, 10.3]
Week 24	8.7 [6.5, 11.3]	6.3 [3.5, 10.3]
ADR Acute kidney injury		
Number of subjects with at least one event, n (%)	45 (8.5)	12 (5.9)
Time to first occurrence (weeks) ^a		
Median (Min-Max)	10.3 (0.1-60.1)	4.9 (0.1-30.3)
Q1-Q3	4.3-24.1	0.2-8.8
Time to first occurrence (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	484 (91.5)	193 (94.1)
Median [95% CI]	NE [NE, NE]	NE [NE, NE]
Q1-Q3	NE-NE	NE-NE
% Event probability estimate [95% CI]		
Week 4	1.7 [0.9, 3.3]	2.5 [1.0, 5.8]
Week 8	3.8 [2.5, 5.8]	4.2 [2.1, 8.3]
Week 12	4.6 [3.1, 6.8]	5.6 [3.0, 10.1]
Week 24	6.5 [4.7, 9.1]	7.1 [3.7, 13.1]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]		
% Event probability estimate [95% CI]		
Week 4	1.7 [0.8, 3.1]	2.4 [0.9, 5.3]
Week 8	3.8 [2.4, 5.7]	3.9 [1.8, 7.2]
Week 12	4.5 [3.0, 6.6]	4.9 [2.5, 8.4]
Week 24	6.2 [4.4, 8.5]	5.4 [2.8, 9.1]
ADR Anaemia		
Number of subjects with at least one event, n (%)	168 (31.8)	27 (13.2)
Time to first occurrence (weeks) ^a		
Median (Min-Max)	12.0 (0.1-60.1)	6.1 (0.1-30.1)
Q1-Q3	4.2-23.7	3.1-17.4
Time to first occurrence (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	361 (68.2)	178 (86.8)
Median [95% CI]	NE [NE, NE]	NE [NE, NE]
Q1-Q3	23.7-NE	30.1-NE
% Event probability estimate [95% CI]		
Week 4	7.8 [5.8, 10.4]	5.0 [2.7, 9.2]

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
ADR Constipation			
Number of subjects with at least one event, n (%)		107 (20.2)	23 (11.2)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		4.3 (0.1-69.1)	4.6 (0.1-25.9)
Q1-Q3		0.6-14.0	2.6-8.7
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		422 (79.8)	182 (88.8)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		9.5 [7.3, 12.3]	4.6 [2.4, 8.6]
Week 8		12.1 [9.6, 15.3]	9.1 [5.8, 14.3]
Week 12		14.1 [11.4, 17.4]	9.8 [6.3, 15.1]
Week 24		18.0 [14.9, 21.7]	14.3 [9.0, 22.4]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		9.5 [7.1, 12.1]	4.4 [2.2, 7.8]
Week 8		12.1 [9.5, 15.0]	8.3 [5.0, 12.6]
Week 12		14.0 [11.2, 17.1]	8.8 [5.4, 13.2]
Week 24		17.4 [14.3, 20.7]	10.2 [6.6, 14.9]
ADR Decreased appetite			
Number of subjects with at least one event, n (%)		113 (21.4)	30 (14.6)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		6.0 (0.1-88.4)	4.7 (0.1-30.3)
Q1-Q3		1.3-12.3	0.9-11.4
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		416 (78.6)	175 (85.4)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		88.4-NE	30.3-NE
% Event probability estimate [95% CI]			
Week 4		8.5 [6.4, 11.2]	6.5 [3.8, 10.9]
Week 8		12.5 [10.0, 15.7]	11.1 [7.4, 16.6]
Week 12		15.5 [12.6, 18.9]	12.8 [8.6, 18.7]
Week 24		18.8 [15.7, 22.5]	19.6 [13.0, 29.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		8.5 [6.3, 11.1]	6.3 [3.5, 10.2]
Week 8		12.5 [9.8, 15.5]	10.2 [6.6, 14.9]
Week 12		15.3 [12.4, 18.5]	11.2 [7.4, 16.0]
Week 24		18.3 [15.2, 21.8]	13.2 [9.0, 18.2]
ADR Diarrhea			
Number of subjects with at least one event, n (%)		101 (19.1)	6 (2.9)
Time to first occurrence (weeks) ^a			

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Median (Min-Max)		7.0 [0.1-103.9]	8.5 [3.0-14.0]
Q1-Q3		2.1-18.3	5.0-13.4
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		428 (80.9)	199 (97.1)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		102.1-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		6.6 [4.8, 9.1]	0.5 [0.1, 3.6]
Week 8		10.3 [8.0, 13.2]	1.7 [0.5, 5.1]
Week 12		12.6 [10.1, 15.8]	2.5 [0.9, 6.6]
Week 24		17.6 [14.5, 21.3]	4.8 [2.1, 11.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		6.6 [4.7, 9.0]	0.5 [0.0, 2.5]
Week 8		10.2 [7.8, 13.0]	1.5 [0.4, 3.9]
Week 12		12.5 [9.8, 15.5]	2.0 [0.6, 4.6]
Week 24		16.6 [13.6, 19.9]	2.9 [1.2, 5.9]
ADR Dizziness			
Number of subjects with at least one event, n (%)		44 (8.3)	9 (4.4)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		9.4 (0.1-113.4)	3.1 (0.1-31.1)
Q1-Q3		1.7-23.6	1.1-6.9
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		485 (91.7)	196 (95.6)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		3.2 [2.0, 5.1]	2.5 [1.0, 5.9]
Week 8		4.0 [2.6, 6.0]	3.7 [1.8, 7.6]
Week 12		4.8 [3.2, 7.0]	4.3 [2.2, 8.5]
Week 24		6.6 [4.7, 9.1]	4.3 [2.2, 8.5]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		3.2 [1.9, 5.0]	2.4 [0.9, 5.3]
Week 8		4.0 [2.5, 5.9]	3.4 [1.5, 6.6]
Week 12		4.7 [3.1, 6.8]	3.9 [1.8, 7.2]
Week 24		6.2 [4.4, 8.5]	3.9 [1.8, 7.2]
ADR Dry eye			
Number of subjects with at least one event, n (%)		16 (3.0)	2 (1.0)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		6.4 (0.1-68.7)	5.1 (0.6-9.6)
Q1-Q3		1.0-24.2	0.6-9.6
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		513 (97.0)	203 (99.0)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		1.5 [0.8, 3.0]	0.5 [0.1, 3.4]
Week 8		1.5 [0.8, 3.0]	0.5 [0.1, 3.4]
Week 12		1.9 [1.0, 3.5]	1.2 [0.3, 4.9]
Week 24		2.4 [1.4, 4.2]	1.2 [0.3, 4.9]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
ADR Dry mouth			
Number of subjects with at least one event, n (%)		208 (39.3)	1 (0.5)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		5.5 (0.1-47.3)	1.1 (1.1-1.1)
Q1-Q3		0.4-13.1	1.1-1.1
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		321 (60.7)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		7.6-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		18.2 [15.1, 21.7]	0.5 [0.1, 3.5]
Week 8		25.5 [22.0, 29.4]	0.5 [0.1, 3.5]
Week 12		28.2 [24.6, 32.3]	0.5 [0.1, 3.5]
Week 24		36.3 [32.3, 40.7]	0.5 [0.1, 3.5]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		18.1 [15.0, 21.6]	0.5 [0.0, 2.5]
Week 8		25.3 [21.7, 29.1]	0.5 [0.0, 2.5]
Week 12		28.0 [24.2, 31.9]	0.5 [0.0, 2.5]
Week 24		34.8 [30.7, 38.9]	0.5 [0.0, 2.5]
ADR Dysgeusia			
Number of subjects with at least one event, n (%)		37 (7.0)	3 (1.5)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		6.3 (0.1-41.4)	3.3 (2.1-6.1)
Q1-Q3		1.3-10.6	2.1-6.1
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		492 (93.0)	202 (98.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		2.6 [1.6, 4.4]	1.0 [0.3, 4.0]
Week 8		4.4 [2.9, 6.5]	1.6 [0.5, 4.9]
Week 12		5.8 [4.1, 8.2]	1.6 [0.5, 4.9]
Week 24		7.1 [5.1, 9.7]	1.6 [0.5, 4.9]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		2.6 [1.5, 4.3]	1.0 [0.2, 3.2]
Week 8		4.3 [2.8, 6.3]	1.5 [0.4, 3.9]
Week 12		5.7 [3.9, 7.9]	1.5 [0.4, 3.9]
Week 24		6.8 [4.9, 9.2]	1.5 [0.4, 3.9]
ADR Fatigue			
Number of subjects with at least one event, n (%)		228 (43.1)	47 (22.9)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		4.9 (0.1-80.0)	5.1 (0.1-27.9)
Q1-Q3		0.4-13.4	2.7-8.9
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		301 (56.9)	158 (77.1)
Median [95% CI]		NE [39.7, NE]	NE [NE, NE]
Q1-Q3		6.1-NE	13.6-NE

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
% Event probability estimate [95% CI]			
Week 4		20.2 [17.1, 23.9]	7.5 [4.6, 12.2]
Week 8		27.5 [23.9, 31.5]	19.0 [14.0, 25.4]
Week 12		30.4 [26.7, 34.5]	22.8 [17.1, 29.9]
Week 24		40.7 [36.5, 45.1]	31.1 [23.4, 40.5]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]	% Event probability estimate [95% CI]		
Week 4		20.2 [16.9, 23.8]	7.3 [4.3, 11.4]
Week 8		27.4 [23.7, 31.3]	17.1 [12.3, 22.5]
Week 12		30.2 [26.4, 34.2]	19.5 [14.4, 25.2]
Week 24		39.1 [35.0, 43.3]	22.4 [17.0, 28.4]
ADR Headache			
Number of subjects with at least one event, n (%)		37 (7.0)	4 (2.0)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		12.9 (0.1-45.0)	6.1 (5.1-12.9)
Q1-Q3		4.9-23.1	5.6-9.5
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		492 (93.0)	201 (98.0)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		1.7 [0.9, 3.2]	0.0 [0.0, 0.0]
Week 8		2.7 [1.6, 4.5]	1.7 [0.6, 5.3]
Week 12		3.2 [2.0, 5.2]	1.7 [0.6, 5.3]
Week 24		5.8 [4.0, 8.3]	2.8 [1.0, 7.6]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]	% Event probability estimate [95% CI]		
Week 4		1.7 [0.8, 3.1]	0.0 [NE, NE]
Week 8		2.6 [1.5, 4.3]	1.5 [0.4, 3.9]
Week 12		3.2 [1.9, 5.0]	1.5 [0.4, 3.9]
Week 24		5.3 [3.6, 7.4]	2.0 [0.6, 4.6]
ADR Leukopenia			
Number of subjects with at least one event, n (%)		83 (15.7)	4 (2.0)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		7.1 (0.1-96.9)	0.1 (0.1-3.0)
Q1-Q3		2.0-16.1	0.1-1.6
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		446 (84.3)	201 (98.0)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		5.3 [3.7, 7.6]	2.0 [0.7, 5.2]
Week 8		8.6 [6.5, 11.3]	2.0 [0.7, 5.2]
Week 12		9.8 [7.5, 12.7]	2.0 [0.7, 5.2]
Week 24		14.5 [11.6, 17.9]	2.0 [0.7, 5.2]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]	% Event probability estimate [95% CI]		
Week 4		5.3 [3.6, 7.4]	2.0 [0.6, 4.6]
Week 8		8.5 [6.3, 11.1]	2.0 [0.6, 4.6]
Week 12		9.6 [7.3, 12.3]	2.0 [0.6, 4.6]
Week 24		13.6 [10.8, 16.7]	2.0 [0.6, 4.6]
ADR Lymphopenia			

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Number of subjects with at least one event, n (%)		75 (14.2)	8 (3.9)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		3.6 (0.1-33.7)	2.2 (0.1-14.0)
Q1-Q3		1.1-12.1	1.0-8.3
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		454 (85.8)	197 (96.1)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		7.6 [5.6, 10.2]	3.0 [1.4, 6.6]
Week 8		9.5 [7.3, 12.3]	3.0 [1.4, 6.6]
Week 12		10.5 [8.1, 13.4]	3.0 [1.4, 6.6]
Week 24		14.2 [11.4, 17.6]	5.3 [2.5, 11.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		7.6 [5.5, 10.0]	2.9 [1.2, 5.9]
Week 8		9.5 [7.1, 12.1]	2.9 [1.2, 5.9]
Week 12		10.4 [8.0, 13.2]	2.9 [1.2, 5.9]
Week 24		13.6 [10.8, 16.7]	3.9 [1.8, 7.2]
ADR Nausea			
Number of subjects with at least one event, n (%)		188 (35.5)	34 (16.6)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		2.0 (0.1-88.4)	5.2 (0.1-31.1)
Q1-Q3		0.3-10.1	2.1-12.1
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		341 (64.5)	171 (83.4)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		7.1-NE	26.6-NE
% Event probability estimate [95% CI]			
Week 4		19.5 [16.4, 23.1]	7.0 [4.2, 11.6]
Week 8		25.2 [21.7, 29.2]	11.6 [7.8, 17.2]
Week 12		28.2 [24.5, 32.2]	13.7 [9.4, 19.7]
Week 24		33.3 [29.4, 37.6]	22.3 [15.7, 31.3]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		19.5 [16.2, 23.0]	6.8 [3.9, 10.8]
Week 8		25.1 [21.5, 28.9]	10.7 [7.0, 15.4]
Week 12		28.0 [24.2, 31.9]	12.2 [8.2, 17.1]
Week 24		32.3 [28.4, 36.3]	15.6 [11.0, 20.9]
ADR Oedema peripheral			
Number of subjects with at least one event, n (%)		52 (9.8)	14 (6.8)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		7.6 (0.1-81.7)	6.8 (0.1-29.4)
Q1-Q3		3.7-17.6	4.1-11.4
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		477 (90.2)	191 (93.2)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		3.0 [1.9, 4.9]	1.5 [0.5, 4.6]
Week 8		4.9 [3.4, 7.2]	5.0 [2.6, 9.4]
Week 12		5.9 [4.2, 8.3]	6.7 [3.7, 11.9]
Week 24		8.3 [6.2, 11.1]	9.0 [5.1, 15.4]

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]	% Event probability estimate [95% CI]		
Week 4	3.0 [1.8, 4.7]	1.5 [0.4, 3.9]	
Week 8	4.9 [3.3, 7.0]	4.4 [2.2, 7.8]	
Week 12	5.9 [4.1, 8.1]	5.4 [2.8, 9.1]	
Week 24	7.9 [5.8, 10.4]	6.3 [3.5, 10.3]	
ADR Pancytopenia	Number of subjects with at least one event, n (%)	9 (1.7)	0
Time to first occurrence (weeks) ^a			
Median (Min-Max)	16.0 (2.7-50.3)		
Q1-Q3	5.0-26.9		
Time to first occurrence (Kaplan-Meier method) (weeks) ^b	No. of censored subjects without event, n (%)	520 (98.3)	205 (100)
Median [95% CI]	NE [NE, NE]	NE [NE, NE]	NE-NE
Q1-Q3	NE-NE	NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4	0.4 [0.1, 1.5]	0.0 [0.0, 0.0]	
Week 8	0.6 [0.2, 1.8]	0.0 [0.0, 0.0]	
Week 12	0.6 [0.2, 1.8]	0.0 [0.0, 0.0]	
Week 24	1.2 [0.5, 2.7]	0.0 [0.0, 0.0]	
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]	% Event probability estimate [95% CI]		
Week 4	0.4 [0.1, 1.3]	0.0 [NE, NE]	
Week 8	0.6 [0.2, 1.6]	0.0 [NE, NE]	
Week 12	0.6 [0.2, 1.6]	0.0 [NE, NE]	
Week 24	1.1 [0.5, 2.4]	0.0 [NE, NE]	
ADR Pyrexia	Number of subjects with at least one event, n (%)	37 (7.0)	7 (3.4)
Time to first occurrence (weeks) ^a			
Median (Min-Max)	10.9 (0.1-99.7)	4.9 (0.1-17.1)	
Q1-Q3	6.6-25.1	0.3-6.1	
Time to first occurrence (Kaplan-Meier method) (weeks) ^b	No. of censored subjects without event, n (%)	492 (93.0)	198 (96.6)
Median [95% CI]	NE [NE, NE]	NE [NE, NE]	NE-NE
Q1-Q3	NE-NE	NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4	1.1 [0.5, 2.5]	1.5 [0.5, 4.6]	
Week 8	2.5 [1.5, 4.2]	3.2 [1.5, 7.0]	
Week 12	3.7 [2.4, 5.7]	3.2 [1.5, 7.0]	
Week 24	5.2 [3.5, 7.5]	4.7 [2.1, 10.6]	
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]	% Event probability estimate [95% CI]		
Week 4	1.1 [0.5, 2.4]	1.5 [0.4, 3.9]	
Week 8	2.5 [1.4, 4.1]	2.9 [1.2, 5.9]	
Week 12	3.6 [2.2, 5.4]	2.9 [1.2, 5.9]	
Week 24	4.9 [3.3, 7.0]	3.4 [1.5, 6.6]	
ADR Thrombocytopenia	Number of subjects with at least one event, n (%)	91 (17.2)	9 (4.4)
Time to first occurrence (weeks) ^a			
Median (Min-Max)	12.0 (0.1-59.1)	5.3 (0.4-9.7)	
Q1-Q3	4.0-21.0	2.9-6.1	
Time to first occurrence (Kaplan-Meier method) (weeks) ^b	No. of censored subjects without event, n (%)	438 (82.8)	196 (95.6)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Adverse Drug Reaction			
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		4.7 [3.2, 6.9]	2.0 [0.8, 5.3]
Week 8		6.1 [4.3, 8.5]	4.3 [2.2, 8.5]
Week 12		8.8 [6.7, 11.6]	5.0 [2.6, 9.5]
Week 24		15.5 [12.5, 19.0]	5.0 [2.6, 9.5]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		4.7 [3.1, 6.8]	2.0 [0.6, 4.6]
Week 8		6.0 [4.2, 8.3]	3.9 [1.8, 7.2]
Week 12		8.7 [6.5, 11.3]	4.4 [2.2, 7.8]
Week 24		14.4 [11.5, 17.5]	4.4 [2.2, 7.8]
ADR Urinary tract infection			
Number of subjects with at least one event, n (%)		62 (11.7)	2 (1.0)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		9.5 (0.1-85.7)	7.1 (5.1-9.0)
Q1-Q3		3.9-21.7	5.1-9.0
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		467 (88.3)	203 (99.0)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		3.0 [1.9, 4.9]	0.0 [0.0, 0.0]
Week 8		5.0 [3.4, 7.2]	0.6 [0.1, 3.9]
Week 12		7.3 [5.4, 9.9]	1.2 [0.3, 4.9]
Week 24		9.6 [7.3, 12.5]	1.2 [0.3, 4.9]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		3.0 [1.8, 4.7]	0.0 [NE, NE]
Week 8		4.9 [3.3, 7.0]	0.5 [0.0, 2.5]
Week 12		7.2 [5.2, 9.6]	1.0 [0.2, 3.2]
Week 24		9.1 [6.8, 11.7]	1.0 [0.2, 3.2]
ADR Vertigo			
Number of subjects with at least one event, n (%)		11 (2.1)	0
Time to first occurrence (weeks) ^a			
Median (Min-Max)		16.1 (0.3-48.0)	
Q1-Q3		4.0-27.4	
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		518 (97.9)	205 (100)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.8]	0.0 [0.0, 0.0]
Week 8		0.6 [0.2, 1.8]	0.0 [0.0, 0.0]
Week 12		0.8 [0.3, 2.0]	0.0 [0.0, 0.0]
Week 24		1.7 [0.8, 3.3]	0.0 [0.0, 0.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.6]	0.0 [NE, NE]
Week 8		0.6 [0.2, 1.6]	0.0 [NE, NE]
Week 12		0.8 [0.3, 1.8]	0.0 [NE, NE]
Week 24		1.5 [0.7, 2.9]	0.0 [NE, NE]

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
ADR Vomiting			
Number of subjects with at least one event, n (%)		101 (19.1)	13 (6.3)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		5.9 (0.1-59.0)	4.9 (0.3-36.3)
Q1-Q3		0.7-14.0	2.9-9.7
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		428 (80.9)	192 (93.7)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		8.5 [6.4, 11.2]	2.5 [1.1, 6.0]
Week 8		11.2 [8.8, 14.2]	4.8 [2.5, 9.0]
Week 12		13.3 [10.7, 16.5]	6.2 [3.5, 11.1]
Week 24		16.6 [13.6, 20.2]	7.8 [4.2, 13.9]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		8.5 [6.3, 11.1]	2.4 [0.9, 5.3]
Week 8		11.2 [8.6, 14.0]	4.4 [2.2, 7.8]
Week 12		13.2 [10.5, 16.3]	5.4 [2.8, 9.1]
Week 24		16.1 [13.1, 19.3]	5.9 [3.2, 9.7]
ADR Weight decreased			
Number of subjects with at least one event, n (%)		58 (11.0)	20 (9.8)
Time to first occurrence (weeks) ^a			
Median (Min-Max)		10.9 (0.1-86.0)	7.9 (0.1-96.4)
Q1-Q3		6.1-19.3	5.2-12.0
Time to first occurrence (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		471 (89.0)	185 (90.2)
Median [95% CI]		NE [NE, NE]	NE [73.3, NE]
Q1-Q3		NE-NE	73.3-NE
% Event probability estimate [95% CI]			
Week 4		1.9 [1.0, 3.5]	2.0 [0.8, 5.3]
Week 8		4.8 [3.3, 7.0]	6.8 [3.9, 11.8]
Week 12		6.4 [4.6, 8.8]	9.2 [5.6, 15.0]
Week 24		9.3 [7.0, 12.2]	11.7 [7.2, 18.7]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		1.9 [1.0, 3.3]	2.0 [0.6, 4.6]
Week 8		4.7 [3.1, 6.8]	5.9 [3.2, 9.7]
Week 12		6.2 [4.4, 8.5]	7.3 [4.3, 11.4]
Week 24		8.7 [6.5, 11.3]	8.3 [5.0, 12.6]

^a Analysis is based on subjects with at least one event.^b Analysis is based on all subjects and censors those without an event.^c Cumulative incidence function considering all treatment discontinuations as competing risks.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-A2-3 2021-09-22 17:06

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Source data: adsl.xpt, addtadr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 ADR update
Table A2-4 Time to first occurrence of grade >=3 adverse drug reaction (FAS safety set)

Adverse Drug Reaction	Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
ADR Abdominal pain		
Number of subjects with at least one event of grade >=3, n (%)	7 (1.3)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a		
Median (Min-Max)	22.4 (0.7-107.1)	4.3 (4.3-4.3)
Q1-Q3	1.3-83.0	4.3-4.3
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	522 (98.7)	204 (99.5)
Median [95% CI]	NE [NE, NE]	NE [NE, NE]
Q1-Q3	NE-NE	NE-NE
% Event probability estimate [95% CI]		
Week 4	0.4 [0.1, 1.5]	0.0 [0.0, 0.0]
Week 8	0.4 [0.1, 1.5]	0.5 [0.1, 3.8]
Week 12	0.6 [0.2, 1.8]	0.5 [0.1, 3.8]
Week 24	0.8 [0.3, 2.2]	0.5 [0.1, 3.8]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]		
% Event probability estimate [95% CI]		
Week 4	0.4 [0.1, 1.3]	0.0 [NE, NE]
Week 8	0.4 [0.1, 1.3]	0.5 [0.0, 2.5]
Week 12	0.6 [0.2, 1.6]	0.5 [0.0, 2.5]
Week 24	0.8 [0.3, 1.8]	0.5 [0.0, 2.5]
ADR Acute kidney injury		
Number of subjects with at least one event of grade >=3, n (%)	17 (3.2)	6 (2.9)
Time to first occurrence of grade >=3 (weeks) ^a		
Median (Min-Max)	18.7 (1.0-60.1)	3.5 (0.1-30.3)
Q1-Q3	8.1-37.7	0.1-8.0
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	512 (96.8)	199 (97.1)
Median [95% CI]	NE [NE, NE]	NE [NE, NE]
Q1-Q3	NE-NE	NE-NE
% Event probability estimate [95% CI]		
Week 4	0.4 [0.1, 1.5]	1.5 [0.5, 4.6]
Week 8	0.8 [0.3, 2.0]	2.7 [1.1, 6.3]
Week 12	1.1 [0.5, 2.5]	2.7 [1.1, 6.3]
Week 24	2.3 [1.3, 4.1]	2.7 [1.1, 6.3]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]		
% Event probability estimate [95% CI]		
Week 4	0.4 [0.1, 1.3]	1.5 [0.4, 3.9]
Week 8	0.8 [0.3, 1.8]	2.4 [0.9, 5.3]
Week 12	1.1 [0.5, 2.4]	2.4 [0.9, 5.3]
Week 24	2.1 [1.1, 3.6]	2.4 [0.9, 5.3]
ADR Anaemia		
Number of subjects with at least one event of grade >=3, n (%)	68 (12.9)	10 (4.9)
Time to first occurrence of grade >=3 (weeks) ^a		
Median (Min-Max)	16.1 (0.1-68.7)	10.1 (3.1-42.1)
Q1-Q3	8.0-29.0	4.3-20.1
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b		
No. of censored subjects without event, n (%)	461 (87.1)	195 (95.1)
Median [95% CI]	NE [NE, NE]	NE [NE, NE]
Q1-Q3	NE-NE	NE-NE
% Event probability estimate [95% CI]		
Week 4	1.7 [0.9, 3.3]	1.0 [0.3, 4.1]

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
ADR Constipation			
Number of subjects with at least one event of grade >=3, n (%)		6 (1.1)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		18.8 (4.1-62.1) 8.9-61.3	2.0 (2.0-2.0) 2.0-2.0
Q1-Q3			
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		523 (98.9)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.0 [0.0, 0.0]	0.5 [0.1, 3.5]
Week 8		0.2 [0.0, 1.3]	0.5 [0.1, 3.5]
Week 12		0.6 [0.2, 1.8]	0.5 [0.1, 3.5]
Week 24		0.6 [0.2, 1.8]	0.5 [0.1, 3.5]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.0 [NE, NE]	0.5 [0.0, 2.5]
Week 8		0.2 [0.0, 1.0]	0.5 [0.0, 2.5]
Week 12		0.6 [0.2, 1.6]	0.5 [0.0, 2.5]
Week 24		0.6 [0.2, 1.6]	0.5 [0.0, 2.5]
ADR Decreased appetite			
Number of subjects with at least one event of grade >=3, n (%)		10 (1.9)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		8.5 (3.3-50.3) 5.7-16.1	4.1 (4.1-4.1) 4.1-4.1
Q1-Q3			
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		519 (98.1)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.4 [0.1, 1.5]	0.0 [0.0, 0.0]
Week 8		0.6 [0.2, 1.8]	0.5 [0.1, 3.8]
Week 12		1.4 [0.6, 2.8]	0.5 [0.1, 3.8]
Week 24		1.6 [0.8, 3.1]	0.5 [0.1, 3.8]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.4 [0.1, 1.3]	0.0 [NE, NE]
Week 8		0.6 [0.2, 1.6]	0.5 [0.0, 2.5]
Week 12		1.3 [0.6, 2.6]	0.5 [0.0, 2.5]
Week 24		1.5 [0.7, 2.9]	0.5 [0.0, 2.5]
ADR Diarrhea			
Number of subjects with at least one event of grade >=3, n (%)		4 (0.8)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Median (Min-Max)		17.9 (4.6-21.0)	5.0 (5.0-5.0)
Q1-Q3		10.6-20.1	5.0-5.0
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		525 (99.2)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 8		0.2 [0.0, 1.3]	0.6 [0.1, 3.9]
Week 12		0.2 [0.0, 1.3]	0.6 [0.1, 3.9]
Week 24		0.9 [0.3, 2.4]	0.6 [0.1, 3.9]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.0 [NE, NE]	0.0 [NE, NE]
Week 8		0.2 [0.0, 1.0]	0.5 [0.0, 2.5]
Week 12		0.2 [0.0, 1.0]	0.5 [0.0, 2.5]
Week 24		0.8 [0.3, 1.8]	0.5 [0.0, 2.5]
ADR Dizziness			
Number of subjects with at least one event of grade >=3, n (%)		5 (0.9)	0
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		4.0 (2.1-81.6)	
Q1-Q3		3.4-28.7	
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		524 (99.1)	205 (100)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.8]	0.0 [0.0, 0.0]
Week 8		0.6 [0.2, 1.8]	0.0 [0.0, 0.0]
Week 12		0.6 [0.2, 1.8]	0.0 [0.0, 0.0]
Week 24		0.6 [0.2, 1.8]	0.0 [0.0, 0.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.6]	0.0 [NE, NE]
Week 8		0.6 [0.2, 1.6]	0.0 [NE, NE]
Week 12		0.6 [0.2, 1.6]	0.0 [NE, NE]
Week 24		0.6 [0.2, 1.6]	0.0 [NE, NE]
ADR Dry eye			
Number of subjects with at least one event of grade >=3, n (%)		0	0
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)			
Q1-Q3			
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		529 (100)	205 (100)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 8		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 12		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 24		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
ADR Dry mouth			
Number of subjects with at least one event of grade >=3, n (%)		0	0
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)			
Q1-Q3			
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		529 (100)	205 (100)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 8		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 12		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 24		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.0 [NE, NE]	0.0 [NE, NE]
Week 8		0.0 [NE, NE]	0.0 [NE, NE]
Week 12		0.0 [NE, NE]	0.0 [NE, NE]
Week 24		0.0 [NE, NE]	0.0 [NE, NE]
ADR Dysgeusia			
Number of subjects with at least one event of grade >=3, n (%)		0	0
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)			
Q1-Q3			
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		529 (100)	205 (100)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 8		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 12		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 24		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.0 [NE, NE]	0.0 [NE, NE]
Week 8		0.0 [NE, NE]	0.0 [NE, NE]
Week 12		0.0 [NE, NE]	0.0 [NE, NE]
Week 24		0.0 [NE, NE]	0.0 [NE, NE]
ADR Fatigue			
Number of subjects with at least one event of grade >=3, n (%)		31 (5.9)	3 (1.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		13.3 (0.1-54.1)	18.1 (11.1-27.9)
Q1-Q3		3.7-23.4	11.1-27.9
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		498 (94.1)	202 (98.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
% Event probability estimate [95% CI]			
Week 4		1.5 [0.8, 3.0]	0.0 [0.0, 0.0]
Week 8		2.1 [1.2, 3.7]	0.0 [0.0, 0.0]
Week 12		2.7 [1.6, 4.5]	0.8 [0.1, 5.8]
Week 24		4.9 [3.3, 7.2]	2.4 [0.6, 10.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		1.5 [0.7, 2.9]	0.0 [NE, NE]
Week 8		2.1 [1.1, 3.6]	0.0 [NE, NE]
Week 12		2.6 [1.5, 4.3]	0.5 [0.0, 2.5]
Week 24		4.5 [3.0, 6.6]	1.0 [0.2, 3.2]
ADR Headache			
Number of subjects with at least one event of grade >=3, n (%)		4 (0.8)	0
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		20.1 (0.1-30.1)	
Q1-Q3		8.2-27.1	
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		525 (99.2)	205 (100)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.2 [0.0, 1.3]	0.0 [0.0, 0.0]
Week 8		0.2 [0.0, 1.3]	0.0 [0.0, 0.0]
Week 12		0.2 [0.0, 1.3]	0.0 [0.0, 0.0]
Week 24		0.7 [0.2, 2.1]	0.0 [0.0, 0.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.2 [0.0, 1.0]	0.0 [NE, NE]
Week 8		0.2 [0.0, 1.0]	0.0 [NE, NE]
Week 12		0.2 [0.0, 1.0]	0.0 [NE, NE]
Week 24		0.6 [0.2, 1.6]	0.0 [NE, NE]
ADR Leukopenia			
Number of subjects with at least one event of grade >=3, n (%)		22 (4.2)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		13.6 (0.7-43.0)	3.0 (3.0-3.0)
Q1-Q3		7.7-31.9	3.0-3.0
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		507 (95.8)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.8]	0.5 [0.1, 3.6]
Week 8		1.1 [0.5, 2.5]	0.5 [0.1, 3.6]
Week 12		1.9 [1.0, 3.6]	0.5 [0.1, 3.6]
Week 24		2.9 [1.7, 4.8]	0.5 [0.1, 3.6]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.6]	0.5 [0.0, 2.5]
Week 8		1.1 [0.5, 2.4]	0.5 [0.0, 2.5]
Week 12		1.9 [1.0, 3.3]	0.5 [0.0, 2.5]
Week 24		2.6 [1.5, 4.3]	0.5 [0.0, 2.5]

ADR Lymphopenia

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Number of subjects with at least one event of grade >=3, n (%)		41 (7.8)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		8.1 [0.9-33.7]	0.1 (0.1-0.1)
Q1-Q3		2.3-13.9	0.1-0.1
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		488 (92.2)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		2.8 [1.7, 4.7]	0.5 [0.1, 3.4]
Week 8		3.8 [2.5, 5.8]	0.5 [0.1, 3.4]
Week 12		5.2 [3.6, 7.4]	0.5 [0.1, 3.4]
Week 24		7.4 [5.4, 10.1]	0.5 [0.1, 3.4]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		2.8 [1.7, 4.5]	0.5 [0.0, 2.5]
Week 8		3.8 [2.4, 5.7]	0.5 [0.0, 2.5]
Week 12		5.1 [3.5, 7.2]	0.5 [0.0, 2.5]
Week 24		7.0 [5.0, 9.4]	0.5 [0.0, 2.5]
ADR Nausea			
Number of subjects with at least one event of grade >=3, n (%)		7 (1.3)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		22.0 (0.3-43.7)	5.0 (5.0-5.0)
Q1-Q3		1.0-29.1	5.0-5.0
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		522 (98.7)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.4 [0.1, 1.5]	0.0 [0.0, 0.0]
Week 8		0.6 [0.2, 1.8]	0.6 [0.1, 3.9]
Week 12		0.6 [0.2, 1.8]	0.6 [0.1, 3.9]
Week 24		1.1 [0.4, 2.6]	0.6 [0.1, 3.9]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.4 [0.1, 1.3]	0.0 [NE, NE]
Week 8		0.6 [0.2, 1.6]	0.5 [0.0, 2.5]
Week 12		0.6 [0.2, 1.6]	0.5 [0.0, 2.5]
Week 24		0.9 [0.4, 2.1]	0.5 [0.0, 2.5]
ADR Oedema peripheral			
Number of subjects with at least one event of grade >=3, n (%)		2 (0.4)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		27.0 (6.4-47.6)	2.9 (2.9-2.9)
Q1-Q3		6.4-47.6	2.9-2.9
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		527 (99.6)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.0 [0.0, 0.0]	0.5 [0.1, 3.6]
Week 8		0.2 [0.0, 1.4]	0.5 [0.1, 3.6]
Week 12		0.2 [0.0, 1.4]	0.5 [0.1, 3.6]
Week 24		0.2 [0.0, 1.4]	0.5 [0.1, 3.6]

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4	0.0 [NE, NE]	0.5 [0.0, 2.5]	
Week 8	0.2 [0.0, 1.0]	0.5 [0.0, 2.5]	
Week 12	0.2 [0.0, 1.0]	0.5 [0.0, 2.5]	
Week 24	0.2 [0.0, 1.0]	0.5 [0.0, 2.5]	
ADR Pancytopenia			
Number of subjects with at least one event of grade >=3, n (%)	7 (1.3)	0	
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)	16.0 (2.7-50.3)		
Q1-Q3	3.9-44.1		
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)	522 (98.7)	205 (100)	
Median [95% CI]	NE [NE, NE]	NE [NE, NE]	
Q1-Q3	NE-NE	NE-NE	
% Event probability estimate [95% CI]			
Week 4	0.4 [0.1, 1.5]	0.0 [0.0, 0.0]	
Week 8	0.6 [0.2, 1.8]	0.0 [0.0, 0.0]	
Week 12	0.6 [0.2, 1.8]	0.0 [0.0, 0.0]	
Week 24	0.8 [0.3, 2.1]	0.0 [0.0, 0.0]	
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4	0.4 [0.1, 1.3]	0.0 [NE, NE]	
Week 8	0.6 [0.2, 1.6]	0.0 [NE, NE]	
Week 12	0.6 [0.2, 1.6]	0.0 [NE, NE]	
Week 24	0.8 [0.3, 1.8]	0.0 [NE, NE]	
ADR Pyrexia			
Number of subjects with at least one event of grade >=3, n (%)	2 (0.4)	0	
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)	8.4 (3.0-13.7)		
Q1-Q3	3.0-13.7		
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)	527 (99.6)	205 (100)	
Median [95% CI]	NE [NE, NE]	NE [NE, NE]	
Q1-Q3	NE-NE	NE-NE	
% Event probability estimate [95% CI]			
Week 4	0.2 [0.0, 1.3]	0.0 [0.0, 0.0]	
Week 8	0.2 [0.0, 1.3]	0.0 [0.0, 0.0]	
Week 12	0.2 [0.0, 1.3]	0.0 [0.0, 0.0]	
Week 24	0.4 [0.1, 1.6]	0.0 [0.0, 0.0]	
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4	0.2 [0.0, 1.0]	0.0 [NE, NE]	
Week 8	0.2 [0.0, 1.0]	0.0 [NE, NE]	
Week 12	0.2 [0.0, 1.0]	0.0 [NE, NE]	
Week 24	0.4 [0.1, 1.3]	0.0 [NE, NE]	
ADR Thrombocytopenia			
Number of subjects with at least one event of grade >=3, n (%)	42 (7.9)	2 (1.0)	
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)	17.1 (0.1-44.0)	6.7 (0.4-13.0)	
Q1-Q3	7.7-23.9	0.4-13.0	
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)	487 (92.1)	203 (99.0)	

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		1.1 [0.5, 2.5]	0.5 [0.1, 3.4]
Week 8		2.3 [1.3, 4.0]	0.5 [0.1, 3.4]
Week 12		3.1 [1.9, 5.0]	0.5 [0.1, 3.4]
Week 24		6.7 [4.8, 9.4]	1.6 [0.4, 6.6]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		1.1 [0.5, 2.4]	0.5 [0.0, 2.5]
Week 8		2.3 [1.2, 3.8]	0.5 [0.0, 2.5]
Week 12		3.0 [1.8, 4.7]	0.5 [0.0, 2.5]
Week 24		6.0 [4.2, 8.3]	1.0 [0.2, 3.2]
ADR Urinary tract infection			
Number of subjects with at least one event of grade >=3, n (%)		20 (3.8)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		9.2 (1.3-47.9)	9.0 (9.0-9.0)
Q1-Q3		5.9-15.9	9.0-9.0
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		509 (96.2)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.8]	0.0 [0.0, 0.0]
Week 8		1.5 [0.8, 3.0]	0.0 [0.0, 0.0]
Week 12		2.5 [1.5, 4.3]	0.7 [0.1, 4.7]
Week 24		3.4 [2.1, 5.4]	0.7 [0.1, 4.7]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.6]	0.0 [NE, NE]
Week 8		1.5 [0.7, 2.9]	0.0 [NE, NE]
Week 12		2.5 [1.4, 4.1]	0.5 [0.0, 2.5]
Week 24		3.2 [1.9, 5.0]	0.5 [0.0, 2.5]
ADR Vertigo			
Number of subjects with at least one event of grade >=3, n (%)		0	0
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)			
Q1-Q3			
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		529 (100)	205 (100)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 8		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 12		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Week 24		0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.0 [NE, NE]	0.0 [NE, NE]
Week 8		0.0 [NE, NE]	0.0 [NE, NE]
Week 12		0.0 [NE, NE]	0.0 [NE, NE]
Week 24		0.0 [NE, NE]	0.0 [NE, NE]

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version	
Adverse Drug Reaction		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)
ADR Vomiting			
Number of subjects with at least one event of grade >=3, n (%)		5 (0.9)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		3.1 (0.3-43.7)	5.0 (5.0-5.0)
Q1-Q3		2.0-22.0	5.0-5.0
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		524 (99.1)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [NE, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.8]	0.0 [0.0, 0.0]
Week 8		0.6 [0.2, 1.8]	0.6 [0.1, 3.9]
Week 12		0.6 [0.2, 1.8]	0.6 [0.1, 3.9]
Week 24		0.8 [0.3, 2.2]	0.6 [0.1, 3.9]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.6 [0.2, 1.6]	0.0 [NE, NE]
Week 8		0.6 [0.2, 1.6]	0.5 [0.0, 2.5]
Week 12		0.6 [0.2, 1.6]	0.5 [0.0, 2.5]
Week 24		0.8 [0.3, 1.8]	0.5 [0.0, 2.5]
ADR Weight decreased			
Number of subjects with at least one event of grade >=3, n (%)		2 (0.4)	1 (0.5)
Time to first occurrence of grade >=3 (weeks) ^a			
Median (Min-Max)		30.1 (0.1-60.1)	89.4 (89.4-89.4)
Q1-Q3		0.1-60.1	89.4-89.4
Time to first occurrence of grade >=3 (Kaplan-Meier method) (weeks) ^b			
No. of censored subjects without event, n (%)		527 (99.6)	204 (99.5)
Median [95% CI]		NE [NE, NE]	NE [89.4, NE]
Q1-Q3		NE-NE	NE-NE
% Event probability estimate [95% CI]			
Week 4		0.2 [0.0, 1.3]	0.0 [0.0, 0.0]
Week 8		0.2 [0.0, 1.3]	0.0 [0.0, 0.0]
Week 12		0.2 [0.0, 1.3]	0.0 [0.0, 0.0]
Week 24		0.2 [0.0, 1.3]	0.0 [0.0, 0.0]
Cumulative incidence function (%) - competing risks analysis ^c [95% CI]			
% Event probability estimate [95% CI]			
Week 4		0.2 [0.0, 1.0]	0.0 [NE, NE]
Week 8		0.2 [0.0, 1.0]	0.0 [NE, NE]
Week 12		0.2 [0.0, 1.0]	0.0 [NE, NE]
Week 24		0.2 [0.0, 1.0]	0.0 [NE, NE]

^a Analysis is based on subjects with at least one event.^b Analysis is based on all subjects and censors those without an event.^c Cumulative incidence function considering all treatment discontinuations as competing risks.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-A2-4 2021-09-22 17:09

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adr.sas

Source data: adsl.xpt, addtadr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company
177Lu-PSMA-617 ADR update

Final Version

Table A2-5 Incidence of randomized treatment-emergent adverse drug reactions (FAS safety set)

	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ADR Fatigue			
Number of patients with at least one event	228 (43.1)	47 (22.9)	275 (37.5)
Maximum grade			
Grade 3 AEs	31 (5.9)	3 (1.5)	34 (4.6)
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
Treatment-related AEs	165 (31.2)	14 (6.8)	179 (24.4)
SAEs	2 (0.4)	0	2 (0.3)
Action taken with PSMA-617			
Drug withdrawn	2 (0.4)	0	2 (0.3)
Dose reduced	2 (0.4)	0	2 (0.3)
Drug interrupted	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	226 (42.7)	47 (22.9)	273 (37.2)
Action taken with BSC/BSoC			
Drug withdrawn	5 (0.9)	0	5 (0.7)
Dose reduced	8 (1.5)	2 (1.0)	10 (1.4)
Drug interrupted	2 (0.4)	1 (0.5)	3 (0.4)
Dose not changed/NA/unknown	216 (40.8)	44 (21.5)	260 (35.4)
AE outcome			
Recovered/resolved	75 (14.2)	4 (2.0)	79 (10.8)
Recovering/resolving	5 (0.9)	2 (1.0)	7 (1.0)
Not recovered/not resolved	161 (30.4)	43 (21.0)	204 (27.8)
Recovered/resolved with sequelae	0	0	0
Fatal	0	0	0
Unknown	1 (0.2)	0	1 (0.1)
ADR Dry mouth			
Number of patients with at least one event	208 (39.3)	1 (0.5)	209 (28.5)
Maximum grade			
Grade 3 AEs	0	0	0
Grade 4 AEs	0	0	0
Grade 5 AEs	0	0	0
Treatment-related AEs	193 (36.5)	0	193 (26.3)
SAEs	0	0	0
Action taken with PSMA-617			
Drug withdrawn	1 (0.2)	0	1 (0.1)
Dose reduced	3 (0.6)	0	3 (0.4)
Drug interrupted	0	0	0
Dose not changed/NA/unknown	205 (38.8)	1 (0.5)	206 (28.1)
Action taken with BSC/BSoC			
Drug withdrawn	1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		207 (39.1)	1 (0.5)	208 (28.3)
AE outcome				
Recovered/resolved		71 (13.4)	1 (0.5)	72 (9.8)
Recovering/resolving		8 (1.5)	0	8 (1.1)
Not recovered/not resolved		137 (25.9)	1 (0.5)	138 (18.8)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		4 (0.8)	0	4 (0.5)
ADR Nausea				
Number of patients with at least one event		188 (35.5)	34 (16.6)	222 (30.2)
Maximum grade				
Grade 3 AEs		7 (1.3)	1 (0.5)	8 (1.1)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		148 (28.0)	8 (3.9)	156 (21.3)
SAEs		3 (0.6)	1 (0.5)	4 (0.5)
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		188 (35.5)	34 (16.6)	222 (30.2)
Action taken with BSC/BSoC				
Drug withdrawn		0	1 (0.5)	1 (0.1)
Dose reduced		1 (0.2)	1 (0.5)	2 (0.3)
Drug interrupted		3 (0.6)	1 (0.5)	4 (0.5)
Dose not changed/NA/unknown		186 (35.2)	31 (15.1)	217 (29.6)
AE outcome				
Recovered/resolved		123 (23.3)	18 (8.8)	141 (19.2)
Recovering/resolving		3 (0.6)	1 (0.5)	4 (0.5)
Not recovered/not resolved		73 (13.8)	18 (8.8)	91 (12.4)
Recovered/resolved with sequelae		1 (0.2)	0	1 (0.1)
Fatal		0	0	0
Unknown		2 (0.4)	0	2 (0.3)
ADR Anaemia				
Number of patients with at least one event		168 (31.8)	27 (13.2)	195 (26.6)
Maximum grade				
Grade 3 AEs		66 (12.5)	10 (4.9)	76 (10.4)
Grade 4 AEs		2 (0.4)	0	2 (0.3)
Grade 5 AEs		0	0	0
Treatment-related AEs		135 (25.5)	6 (2.9)	141 (19.2)
SAEs		15 (2.8)	1 (0.5)	16 (2.2)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Action taken with PSMA-617				
Drug withdrawn		15 (2.8)	1 (0.5)	16 (2.2)
Dose reduced		7 (1.3)	0	7 (1.0)
Drug interrupted		27 (5.1)	1 (0.5)	28 (3.8)
Dose not changed/NA/unknown		151 (28.5)	26 (12.7)	177 (24.1)
Action taken with BSC/BSoC				
Drug withdrawn		5 (0.9)	0	5 (0.7)
Dose reduced		0	0	0
Drug interrupted		9 (1.7)	0	9 (1.2)
Dose not changed/NA/unknown		161 (30.4)	27 (13.2)	188 (25.6)
AE outcome				
Recovered/resolved		54 (10.2)	11 (5.4)	65 (8.9)
Recovering/resolving		1 (0.2)	1 (0.5)	2 (0.3)
Not recovered/not resolved		125 (23.6)	18 (8.8)	143 (19.5)
Recovered/resolved with sequelae		1 (0.2)	0	1 (0.1)
Fatal		0	0	0
Unknown		0	0	0
ADR Decreased appetite				
Number of patients with at least one event		113 (21.4)	30 (14.6)	143 (19.5)
Maximum grade				
Grade 3 AEs		9 (1.7)	1 (0.5)	10 (1.4)
Grade 4 AEs		1 (0.2)	0	1 (0.1)
Grade 5 AEs		0	0	0
Treatment-related AEs		68 (12.9)	6 (2.9)	74 (10.1)
SAEs		1 (0.2)	0	1 (0.1)
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		112 (21.2)	30 (14.6)	142 (19.3)
Action taken with BSC/BSoC				
Drug withdrawn		2 (0.4)	0	2 (0.3)
Dose reduced		0	1 (0.5)	1 (0.1)
Drug interrupted		0	0	0
Dose not changed/NA/unknown		111 (21.0)	29 (14.1)	140 (19.1)
AE outcome				
Recovered/resolved		44 (8.3)	8 (3.9)	52 (7.1)
Recovering/resolving		7 (1.3)	0	7 (1.0)
Not recovered/not resolved		70 (13.2)	22 (10.7)	92 (12.5)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0
ADR Constipation				
Number of patients with at least one event		107 (20.2)	23 (11.2)	130 (17.7)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Maximum grade				
Grade 3 AEs		5 (0.9)	1 (0.5)	6 (0.8)
Grade 4 AEs		1 (0.2)	0	1 (0.1)
Grade 5 AEs		0	0	0
Treatment-related AEs		46 (8.7)	1 (0.5)	47 (6.4)
SAEs		5 (0.9)	1 (0.5)	6 (0.8)
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		106 (20.0)	23 (11.2)	129 (17.6)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		106 (20.0)	23 (11.2)	129 (17.6)
AE outcome				
Recovered/resolved		66 (12.5)	7 (3.4)	73 (9.9)
Recovering/resolving		4 (0.8)	1 (0.5)	5 (0.7)
Not recovered/not resolved		48 (9.1)	17 (8.3)	65 (8.9)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		2 (0.4)	0	2 (0.3)
ADR Diarrhea				
Number of patients with at least one event		101 (19.1)	6 (2.9)	107 (14.6)
Maximum grade				
Grade 3 AEs		4 (0.8)	1 (0.5)	5 (0.7)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		58 (11.0)	0	58 (7.9)
SAEs		0	1 (0.5)	1 (0.1)
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		2 (0.4)	0	2 (0.3)
Dose not changed/NA/unknown		101 (19.1)	6 (2.9)	107 (14.6)
Action taken with BSC/BSoC				
Drug withdrawn		1 (0.2)	0	1 (0.1)
Dose reduced		0	0	0
Drug interrupted		2 (0.4)	0	2 (0.3)
Dose not changed/NA/unknown		99 (18.7)	6 (2.9)	105 (14.3)
AE outcome				
Recovered/resolved		78 (14.7)	5 (2.4)	83 (11.3)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Recovering/resolving		3 (0.6)	0	3 (0.4)
Not recovered/not resolved		25 (4.7)	1 (0.5)	26 (3.5)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0
ADR Vomiting				
Number of patients with at least one event		101 (19.1)	13 (6.3)	114 (15.5)
Maximum grade				
Grade 3 AEs		5 (0.9)	1 (0.5)	6 (0.8)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		63 (11.9)	3 (1.5)	66 (9.0)
SAEs		5 (0.9)	1 (0.5)	6 (0.8)
Action taken with PSMA-617				
Drug withdrawn		1 (0.2)	0	1 (0.1)
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		100 (18.9)	13 (6.3)	113 (15.4)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0
Dose reduced		1 (0.2)	0	1 (0.1)
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		100 (18.9)	13 (6.3)	113 (15.4)
AE outcome				
Recovered/resolved		80 (15.1)	11 (5.4)	91 (12.4)
Recovering/resolving		0	0	0
Not recovered/not resolved		27 (5.1)	2 (1.0)	29 (4.0)
Recovered/resolved with sequelae		1 (0.2)	0	1 (0.1)
Fatal		0	0	0
Unknown		0	0	0
ADR Thrombocytopenia				
Number of patients with at least one event		91 (17.2)	9 (4.4)	100 (13.6)
Maximum grade				
Grade 3 AEs		30 (5.7)	2 (1.0)	32 (4.4)
Grade 4 AEs		12 (2.3)	0	12 (1.6)
Grade 5 AEs		0	0	0
Treatment-related AEs		83 (15.7)	0	83 (11.3)
SAEs		3 (0.6)	0	3 (0.4)
Action taken with PSMA-617				
Drug withdrawn		15 (2.8)	0	15 (2.0)
Dose reduced		10 (1.9)	0	10 (1.4)
Drug interrupted		19 (3.6)	0	19 (2.6)
Dose not changed/NA/unknown		79 (14.9)	9 (4.4)	88 (12.0)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Action taken with BSC/BSoC				
Drug withdrawn		5 (0.9)	0	5 (0.7)
Dose reduced		0	0	0
Drug interrupted		3 (0.6)	0	3 (0.4)
Dose not changed/NA/unknown		89 (16.8)	9 (4.4)	98 (13.4)
AE outcome				
Recovered/resolved		25 (4.7)	1 (0.5)	26 (3.5)
Recovering/resolving		1 (0.2)	0	1 (0.1)
Not recovered/not resolved		72 (13.6)	8 (3.9)	80 (10.9)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		1 (0.2)	0	1 (0.1)
ADR Leukopenia				
Number of patients with at least one event		83 (15.7)	4 (2.0)	87 (11.9)
Maximum grade				
Grade 3 AEs		18 (3.4)	1 (0.5)	19 (2.6)
Grade 4 AEs		4 (0.8)	0	4 (0.5)
Grade 5 AEs		0	0	0
Treatment-related AEs		75 (14.2)	3 (1.5)	78 (10.6)
SAEs		2 (0.4)	0	2 (0.3)
Action taken with PSMA-617				
Drug withdrawn		9 (1.7)	0	9 (1.2)
Dose reduced		6 (1.1)	0	6 (0.8)
Drug interrupted		11 (2.1)	0	11 (1.5)
Dose not changed/NA/unknown		78 (14.7)	4 (2.0)	82 (11.2)
Action taken with BSC/BSoC				
Drug withdrawn		2 (0.4)	0	2 (0.3)
Dose reduced		0	0	0
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		82 (15.5)	4 (2.0)	86 (11.7)
AE outcome				
Recovered/resolved		58 (11.0)	1 (0.5)	59 (8.0)
Recovering/resolving		2 (0.4)	0	2 (0.3)
Not recovered/not resolved		33 (6.2)	3 (1.5)	36 (4.9)
Recovered/resolved with sequelae		1 (0.2)	0	1 (0.1)
Fatal		0	0	0
Unknown		0	0	0
ADR Lymphopenia				
Number of patients with at least one event		75 (14.2)	8 (3.9)	83 (11.3)
Maximum grade				
Grade 3 AEs		37 (7.0)	1 (0.5)	38 (5.2)
Grade 4 AEs		4 (0.8)	0	4 (0.5)
Grade 5 AEs		0	0	0

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Treatment-related AEs		61 (11.5)	2 (1.0)	63 (8.6)
SAEs		0	0	0
Action taken with PSMA-617				
Drug withdrawn		2 (0.4)	0	2 (0.3)
Dose reduced		2 (0.4)	0	2 (0.3)
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		73 (13.8)	8 (3.9)	81 (11.0)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		2 (0.4)	0	2 (0.3)
Dose not changed/NA/unknown		75 (14.2)	8 (3.9)	83 (11.3)
AE outcome				
Recovered/resolved		35 (6.6)	5 (2.4)	40 (5.4)
Recovering/resolving		1 (0.2)	0	1 (0.1)
Not recovered/not resolved		47 (8.9)	4 (2.0)	51 (6.9)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0
ADR Urinary tract infection				
Number of patients with at least one event		62 (11.7)	2 (1.0)	64 (8.7)
Maximum grade				
Grade 3 AEs		20 (3.8)	1 (0.5)	21 (2.9)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		4 (0.8)	0	4 (0.5)
SAEs		13 (2.5)	1 (0.5)	14 (1.9)
Action taken with PSMA-617				
Drug withdrawn		1 (0.2)	0	1 (0.1)
Dose reduced		0	0	0
Drug interrupted		2 (0.4)	0	2 (0.3)
Dose not changed/NA/unknown		61 (11.5)	2 (1.0)	63 (8.6)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		3 (0.6)	0	3 (0.4)
Dose not changed/NA/unknown		61 (11.5)	2 (1.0)	63 (8.6)
AE outcome				
Recovered/resolved		54 (10.2)	2 (1.0)	56 (7.6)
Recovering/resolving		0	0	0
Not recovered/not resolved		14 (2.6)	0	14 (1.9)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
ADR Abdominal pain				
Number of patients with at least one event		61 (11.5)	13 (6.3)	74 (10.1)
Maximum grade				
Grade 3 AEs		7 (1.3)	1 (0.5)	8 (1.1)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		20 (3.8)	3 (1.5)	23 (3.1)
SAEs		5 (0.9)	1 (0.5)	6 (0.8)
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		61 (11.5)	13 (6.3)	74 (10.1)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		60 (11.3)	13 (6.3)	73 (9.9)
AE outcome				
Recovered/resolved		44 (8.3)	6 (2.9)	50 (6.8)
Recovering/resolving		2 (0.4)	1 (0.5)	3 (0.4)
Not recovered/not resolved		17 (3.2)	5 (2.4)	22 (3.0)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0
ADR Weight decreased				
Number of patients with at least one event		58 (11.0)	20 (9.8)	78 (10.6)
Maximum grade				
Grade 3 AEs		2 (0.4)	1 (0.5)	3 (0.4)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		24 (4.5)	2 (1.0)	26 (3.5)
SAEs		0	0	0
Action taken with PSMA-617				
Drug withdrawn		2 (0.4)	0	2 (0.3)
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		56 (10.6)	20 (9.8)	76 (10.4)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		58 (11.0)	20 (9.8)	78 (10.6)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
AE outcome				
Recovered/resolved		12 (2.3)	5 (2.4)	17 (2.3)
Recovering/resolving		3 (0.6)	1 (0.5)	4 (0.5)
Not recovered/not resolved		43 (8.1)	16 (7.8)	59 (8.0)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0
ADR Oedema peripheral				
Number of patients with at least one event		52 (9.8)	14 (6.8)	66 (9.0)
Maximum grade				
Grade 3 AEs		2 (0.4)	1 (0.5)	3 (0.4)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		16 (3.0)	1 (0.5)	17 (2.3)
SAEs		1 (0.2)	0	1 (0.1)
Action taken with PSMA-617				
Drug withdrawn		1 (0.2)	0	1 (0.1)
Dose reduced		0	0	0
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		50 (9.5)	14 (6.8)	64 (8.7)
Action taken with BSC/BSoC				
Drug withdrawn		1 (0.2)	0	1 (0.1)
Dose reduced		0	1 (0.5)	1 (0.1)
Drug interrupted		0	1 (0.5)	1 (0.1)
Dose not changed/NA/unknown		51 (9.6)	13 (6.3)	64 (8.7)
AE outcome				
Recovered/resolved		22 (4.2)	6 (2.9)	28 (3.8)
Recovering/resolving		2 (0.4)	0	2 (0.3)
Not recovered/not resolved		28 (5.3)	9 (4.4)	37 (5.0)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0
ADR Acute kidney injury				
Number of patients with at least one event		45 (8.5)	12 (5.9)	57 (7.8)
Maximum grade				
Grade 3 AEs		17 (3.2)	6 (2.9)	23 (3.1)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		18 (3.4)	0	18 (2.5)
SAEs		9 (1.7)	7 (3.4)	16 (2.2)
Action taken with PSMA-617				
Drug withdrawn		1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Dose reduced		2 (0.4)	0	2 (0.3)
Drug interrupted		2 (0.4)	0	2 (0.3)
Dose not changed/NA/unknown		41 (7.8)	12 (5.9)	53 (7.2)
Action taken with BSC/BSoC				
Drug withdrawn		0	1 (0.5)	1 (0.1)
Dose reduced		1 (0.2)	0	1 (0.1)
Drug interrupted		1 (0.2)	2 (1.0)	3 (0.4)
Dose not changed/NA/unknown		43 (8.1)	10 (4.9)	53 (7.2)
AE outcome				
Recovered/resolved		28 (5.3)	8 (3.9)	36 (4.9)
Recovering/resolving		1 (0.2)	1 (0.5)	2 (0.3)
Not recovered/not resolved		18 (3.4)	3 (1.5)	21 (2.9)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		1 (0.2)	1 (0.5)	2 (0.3)
ADR Dizziness				
Number of patients with at least one event		44 (8.3)	9 (4.4)	53 (7.2)
Maximum grade				
Grade 3 AEs		5 (0.9)	0	5 (0.7)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		13 (2.5)	2 (1.0)	15 (2.0)
SAEs		2 (0.4)	0	2 (0.3)
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		44 (8.3)	9 (4.4)	53 (7.2)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		1 (0.2)	1 (0.5)	2 (0.3)
Dose not changed/NA/unknown		43 (8.1)	8 (3.9)	51 (6.9)
AE outcome				
Recovered/resolved		26 (4.9)	4 (2.0)	30 (4.1)
Recovering/resolving		2 (0.4)	0	2 (0.3)
Not recovered/not resolved		19 (3.6)	5 (2.4)	24 (3.3)
Recovered/resolved with sequelae		1 (0.2)	0	1 (0.1)
Fatal		0	0	0
Unknown		0	0	0
ADR Dysgeusia				
Number of patients with at least one event		37 (7.0)	3 (1.5)	40 (5.4)
Maximum grade				
Grade 3 AEs		0	0	0

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		32 (6.0)	2 (1.0)	34 (4.6)
SAEs		0	0	0
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		37 (7.0)	3 (1.5)	40 (5.4)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		37 (7.0)	3 (1.5)	40 (5.4)
AE outcome				
Recovered/resolved		13 (2.5)	0	13 (1.8)
Recovering/resolving		0	0	0
Not recovered/not resolved		27 (5.1)	3 (1.5)	30 (4.1)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0
ADR Headache				
Number of patients with at least one event		37 (7.0)	4 (2.0)	41 (5.6)
Maximum grade				
Grade 3 AEs		4 (0.8)	0	4 (0.5)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		11 (2.1)	1 (0.5)	12 (1.6)
SAEs		2 (0.4)	0	2 (0.3)
Action taken with PSMA-617				
Drug withdrawn		1 (0.2)	0	1 (0.1)
Dose reduced		0	0	0
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		36 (6.8)	4 (2.0)	40 (5.4)
Action taken with BSC/BSoC				
Drug withdrawn		1 (0.2)	0	1 (0.1)
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		36 (6.8)	4 (2.0)	40 (5.4)
AE outcome				
Recovered/resolved		21 (4.0)	1 (0.5)	22 (3.0)
Recovering/resolving		0	0	0
Not recovered/not resolved		16 (3.0)	3 (1.5)	19 (2.6)
Recovered/resolved with sequelae		1 (0.2)	0	1 (0.1)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Fatal		0	0	0
Unknown		0	0	0
ADR Pyrexia				
Number of patients with at least one event		37 (7.0)	7 (3.4)	44 (6.0)
Maximum grade				
Grade 3 AEs		2 (0.4)	0	2 (0.3)
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		4 (0.8)	1 (0.5)	5 (0.7)
SAEs		8 (1.5)	0	8 (1.1)
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		2 (0.4)	0	2 (0.3)
Dose not changed/NA/unknown		35 (6.6)	7 (3.4)	42 (5.7)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown		36 (6.8)	7 (3.4)	43 (5.9)
AE outcome				
Recovered/resolved		36 (6.8)	5 (2.4)	41 (5.6)
Recovering/resolving		0	0	0
Not recovered/not resolved		1 (0.2)	2 (1.0)	3 (0.4)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0
ADR Dry eye				
Number of patients with at least one event		16 (3.0)	2 (1.0)	18 (2.5)
Maximum grade				
Grade 3 AEs		0	0	0
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		13 (2.5)	1 (0.5)	14 (1.9)
SAEs		0	0	0
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		16 (3.0)	2 (1.0)	18 (2.5)
Action taken with BSC/BSoC				
Drug withdrawn		0	0	0

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update		Final Version		
		Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Dose reduced		1 (0.2)	0	1 (0.1)
Drug interrupted		0	0	0
Dose not changed/NA/unknown		15 (2.8)	2 (1.0)	17 (2.3)
AE outcome				
Recovered/resolved		8 (1.5)	0	8 (1.1)
Recovering/resolving		0	0	0
Not recovered/not resolved		9 (1.7)	2 (1.0)	11 (1.5)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		1 (0.2)	0	1 (0.1)
ADR Vertigo				
Number of patients with at least one event		11 (2.1)	0	11 (1.5)
Maximum grade				
Grade 3 AEs		0	0	0
Grade 4 AEs		0	0	0
Grade 5 AEs		0	0	0
Treatment-related AEs		1 (0.2)	0	1 (0.1)
SAEs		1 (0.2)	0	1 (0.1)
Action taken with PSMA-617				
Drug withdrawn		0	0	0
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		11 (2.1)	0	11 (1.5)
Action taken with BSC/BSoC				
Drug withdrawn		1 (0.2)	0	1 (0.1)
Dose reduced		0	0	0
Drug interrupted		0	0	0
Dose not changed/NA/unknown		10 (1.9)	0	10 (1.4)
AE outcome				
Recovered/resolved		6 (1.1)	0	6 (0.8)
Recovering/resolving		0	0	0
Not recovered/not resolved		5 (0.9)	0	5 (0.7)
Recovered/resolved with sequelae		0	0	0
Fatal		0	0	0
Unknown		0	0	0
ADR Pancytopenia				
Number of patients with at least one event		9 (1.7)	0	9 (1.2)
Maximum grade				
Grade 3 AEs		3 (0.6)	0	3 (0.4)
Grade 4 AEs		2 (0.4)	0	2 (0.3)
Grade 5 AEs		2 (0.4)	0	2 (0.3)
Treatment-related AEs		7 (1.3)	0	7 (1.0)
SAEs		6 (1.1)	0	6 (0.8)

Advanced Accelerator Applications, a Novartis Company 177Lu-PSMA-617 ADR update	Final Version		
	Lu-PSMA-617 +BSC/BSoC (N=529) n (%)	BSC/BSoC only (N=205) n (%)	Overall (N=734) n (%)
Action taken with PSMA-617			
Drug withdrawn	3 (0.6)	0	3 (0.4)
Dose reduced	0	0	0
Drug interrupted	0	0	0
Dose not changed/NA/unknown	6 (1.1)	0	6 (0.8)
Action taken with BSC/BSoC			
Drug withdrawn	2 (0.4)	0	2 (0.3)
Dose reduced	0	0	0
Drug interrupted	1 (0.2)	0	1 (0.1)
Dose not changed/NA/unknown	6 (1.1)	0	6 (0.8)
AE outcome			
Recovered/resolved	1 (0.2)	0	1 (0.1)
Recovering/resolving	0	0	0
Not recovered/not resolved	3 (0.6)	0	3 (0.4)
Recovered/resolved with sequelae	1 (0.2)	0	1 (0.1)
Fatal	2 (0.4)	0	2 (0.3)
Unknown	2 (0.4)	0	2 (0.3)

Results given as xx (XX.x) [xx] where xx=frequency, (xx.x)=percentage

A patient may be counted in several rows for action taken and outcome.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

Output ID: T-A2-5 2021-09-22 23:31

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adr.sas

Source data: adsl.xpt, adadr.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 ADR update

Table A2-6 Worsening from baseline - worst hematology abnormalities based on CTCAE grades and frequency category - Lu-PSMA-617+BSC/BSoC arm (FAS safety set)

Parameter (unit)	Number of subjects m	Lu-PSMA-617+BSC/BSoC (N=529)				Frequency category All grades
		All grades n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 3/4 n (%)	
Eosinophils (10E9/L) High	494	27 (5.5)	0	0	0	Common
Hemoglobin (g/L) Low	529	336 (63.5)	79 (14.9)	0	79 (14.9)	Very common
Hemoglobin (g/L) High	529	1 (0.2)	0	0	0	Uncommon
Lymphocytes (10E9/L) Low	506	428 (84.6)	209 (41.3)	28 (5.5)	237 (46.8)	Very common
Lymphocytes (10E9/L) High	506	2 (0.4)	2 (0.4)	0	2 (0.4)	Uncommon
Neutrophils (10E9/L) Low	508	140 (27.6)	21 (4.1)	2 (0.4)	23 (4.5)	Very common
Platelets (10E9/L) Low	529	236 (44.6)	37 (7.0)	12 (2.3)	49 (9.3)	Very common
Leukocytes (10E9/L) Low	529	294 (55.6)	34 (6.4)	2 (0.4)	36 (6.8)	Very common

n: represent counts of subjects

m: number of subjects with baseline and post-baseline values. Percentages are based on m.

Worsened post-baseline value is considered when a subject had a worst post-baseline grade observed higher than baseline grade. Only the worst grade is reported in this table.

All grades represents subjects with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Frequency category is based on the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$).

Output ID: T-A2-6 2021-09-22 16:58

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGMT-lb-worst.sas

Source data: adsl.xpt, adlb.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 ADR update

Table A2-7 Worsening from baseline - worst biochemistry abnormalities based on CTCAE grades and frequency category - Lu-PSMA-617+BSC/BSoC arm (FAS safety set)

Parameter (unit)	Number of subjects m	Lu-PSMA-617+BSC/BSoC (N=529)				Frequency category All grades
		All grades n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 3/4 n (%)	
Albumin (g/L) Low	528	187 (35.4)	3 (0.6)	0	3 (0.6)	Very common
Alkaline phosphatase (IU/L) High	528	112 (21.2)	4 (0.8)	0	4 (0.8)	Very common
Alanine aminotransferase (IU/L) High	528	101 (19.1)	7 (1.3)	1 (0.2)	8 (1.5)	Very common
Aspartate aminotransferase (IU/L) High	526	150 (28.5)	5 (1.0)	1 (0.2)	6 (1.1)	Very common
Bilirubin (umol/L) High	528	47 (8.9)	4 (0.8)	0	4 (0.8)	Common
Calcium (mmol/L) Low	525	207 (39.4)	7 (1.3)	6 (1.1)	13 (2.5)	Very common
Calcium (mmol/L) High	525	51 (9.7)	0	3 (0.6)	3 (0.6)	Common
Creatinine (umol/L) High	529	131 (24.8)	5 (0.9)	0	5 (0.9)	Very common
Glucose (mmol/L) Low	529	47 (8.9)	0	0	0	Common
Potassium (mmol/L) Low	529	82 (15.5)	6 (1.1)	1 (0.2)	7 (1.3)	Very common
Potassium (mmol/L) High	529	129 (24.4)	2 (0.4)	1 (0.2)	3 (0.6)	Very common
Lactate dehydrogenase (IU/L) High	527	140 (26.6)	0	0	0	Very common
Sodium (mmol/L) Low	529	179 (33.8)	3 (0.6)	0	3 (0.6)	Very common
Sodium (mmol/L) High	529	58 (11.0)	0	0	0	Very common

n: represent counts of subjects

m: number of subjects with baseline and post-baseline values. Percentages are based on m.
 Worsened post-baseline value is considered when a subject had a worst post-baseline grade observed higher than baseline grade. Only the worst grade is reported in this table.

All grades represents subjects with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Frequency category is based on the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$).

Output ID: T-A2-7 2021-09-22 16:58

...\\BIOMETRY\\PROJECTS\\PSMA617\\VISION\\SAFETY_UPDATE_90DAYS\\PRODUCTION\\TLF\\PGM\\t-lb-worst.sas

Source data: adsl.xpt, adlb.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 ADR update

Table A2-8 Worsening from baseline - worst hematology abnormalities based on CTCAE grades and frequency category - BSC/BSoC only arm (FAS safety set)

Parameter (unit)	Number of subjects m	BSC/BSoC only (N=205)				Frequency category All grades
		All grades n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 3/4 n (%)	
Eosinophils (10E9/L) High	193	14 (7.3)	0	0	0	Common
Hemoglobin (g/L) Low	198	68 (34.3)	13 (6.6)	0	13 (6.6)	Very common
Hemoglobin (g/L) High	198	0	0	0	0	Very rare
Lymphocytes (10E9/L) Low	194	98 (50.5)	32 (16.5)	2 (1.0)	34 (17.5)	Very common
Lymphocytes (10E9/L) High	194	2 (1.0)	0	0	0	Common
Neutrophils (10E9/L) Low	196	17 (8.7)	0	1 (0.5)	1 (0.5)	Common
Platelets (10E9/L) Low	198	40 (20.2)	3 (1.5)	2 (1.0)	5 (2.5)	Very common
Leukocytes (10E9/L) Low	198	44 (22.2)	3 (1.5)	1 (0.5)	4 (2.0)	Very common

n: represent counts of subjects

m: number of subjects with baseline and post-baseline values. Percentages are based on m.

Worsened post-baseline value is considered when a subject had a worst post-baseline grade observed higher than baseline grade. Only the worst grade is reported in this table.

All grades represents subjects with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Frequency category is based on the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$).

Output ID: T-A2-8 2021-09-22 16:58

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Source data: adsl.xpt, adlb.xpt

Data Cutoff Date: 28JUN2021

Advanced Accelerator Applications, a Novartis Company

Final Version

177Lu-PSMA-617 ADR update

Table A2-9 Worsening from baseline - worst biochemistry abnormalities based on CTCAE grades and frequency category - BSC/BSoC only arm (FAS safety set)

Parameter (unit)	Number of subjects m	BSC/BSoC only (N=205)				Frequency category All grades
		All grades n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 3/4 n (%)	
Albumin (g/L) Low	198	68 (34.3)	0	0	0	Very common
Alkaline phosphatase (IU/L) High	197	41 (20.8)	2 (1.0)	0	2 (1.0)	Very common
Alanine aminotransferase (IU/L) High	198	30 (15.2)	2 (1.0)	0	2 (1.0)	Very common
Aspartate aminotransferase (IU/L) High	197	35 (17.8)	2 (1.0)	0	2 (1.0)	Very common
Bilirubin (umol/L) High	198	28 (14.1)	1 (0.5)	0	1 (0.5)	Very common
Calcium (mmol/L) Low	198	55 (27.8)	4 (2.0)	2 (1.0)	6 (3.0)	Very common
Calcium (mmol/L) High	198	13 (6.6)	1 (0.5)	0	1 (0.5)	Common
Creatinine (umol/L) High	198	28 (14.1)	1 (0.5)	0	1 (0.5)	Very common
Glucose (mmol/L) Low	197	10 (5.1)	0	0	0	Common
Potassium (mmol/L) Low	197	28 (14.2)	0	0	0	Very common
Potassium (mmol/L) High	197	35 (17.8)	1 (0.5)	0	1 (0.5)	Very common
Lactate dehydrogenase (IU/L) High	193	44 (22.8)	0	0	0	Very common
Sodium (mmol/L) Low	198	45 (22.7)	1 (0.5)	1 (0.5)	2 (1.0)	Very common
Sodium (mmol/L) High	198	10 (5.1)	0	0	0	Common

n: represent counts of subjects

m: number of subjects with baseline and post-baseline values. Percentages are based on m.

Worsened post-baseline value is considered when a subject had a worst post-baseline grade observed higher than baseline grade. Only the worst grade is reported in this table.

All grades represents subjects with any grade 1, 2, 3 or 4 post-baseline.

Grades based on CTCAE version 5.0.

Frequency category is based on the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$).

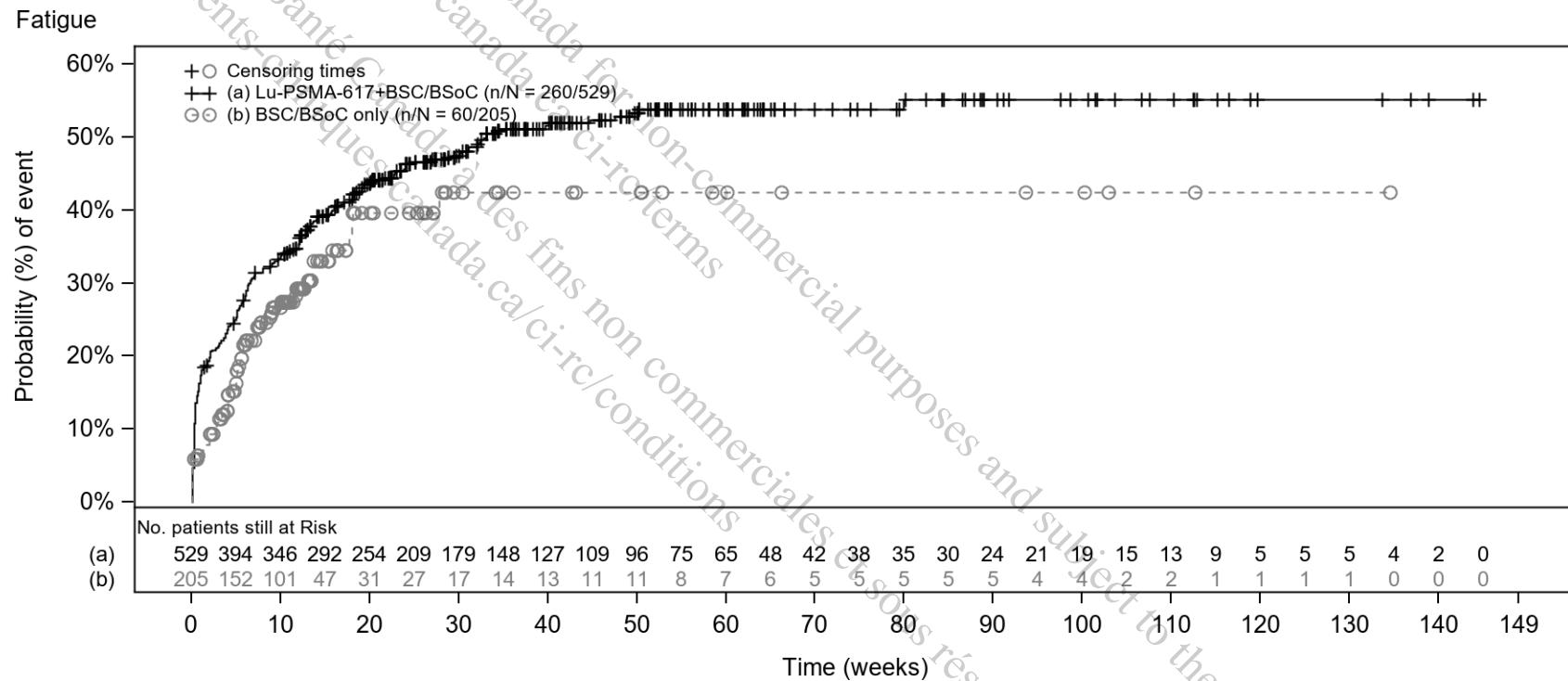
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Source data: adsl.xpt, adlb.xpt

Data Cutoff Date: 28JUN2021

Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



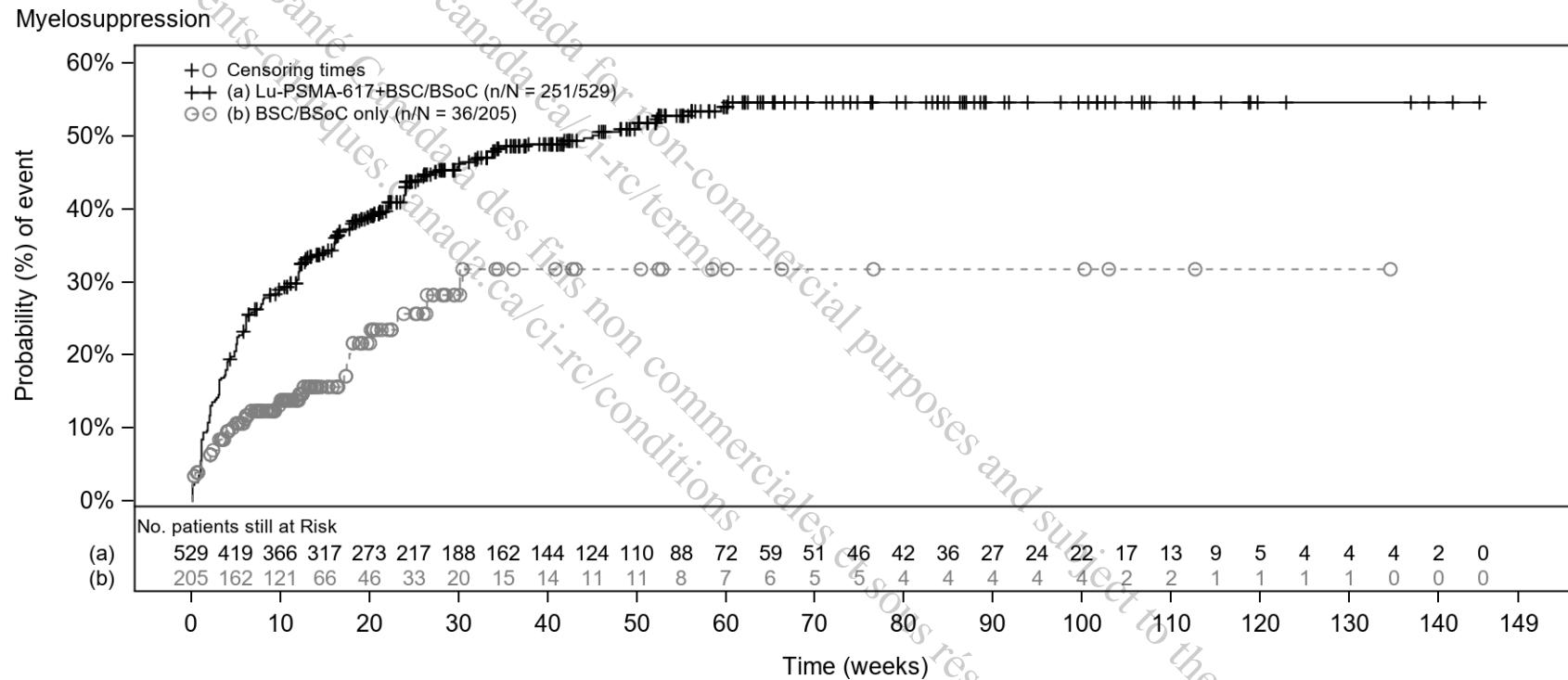
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Source data: adsl.xpt, adtte.xpt

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Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



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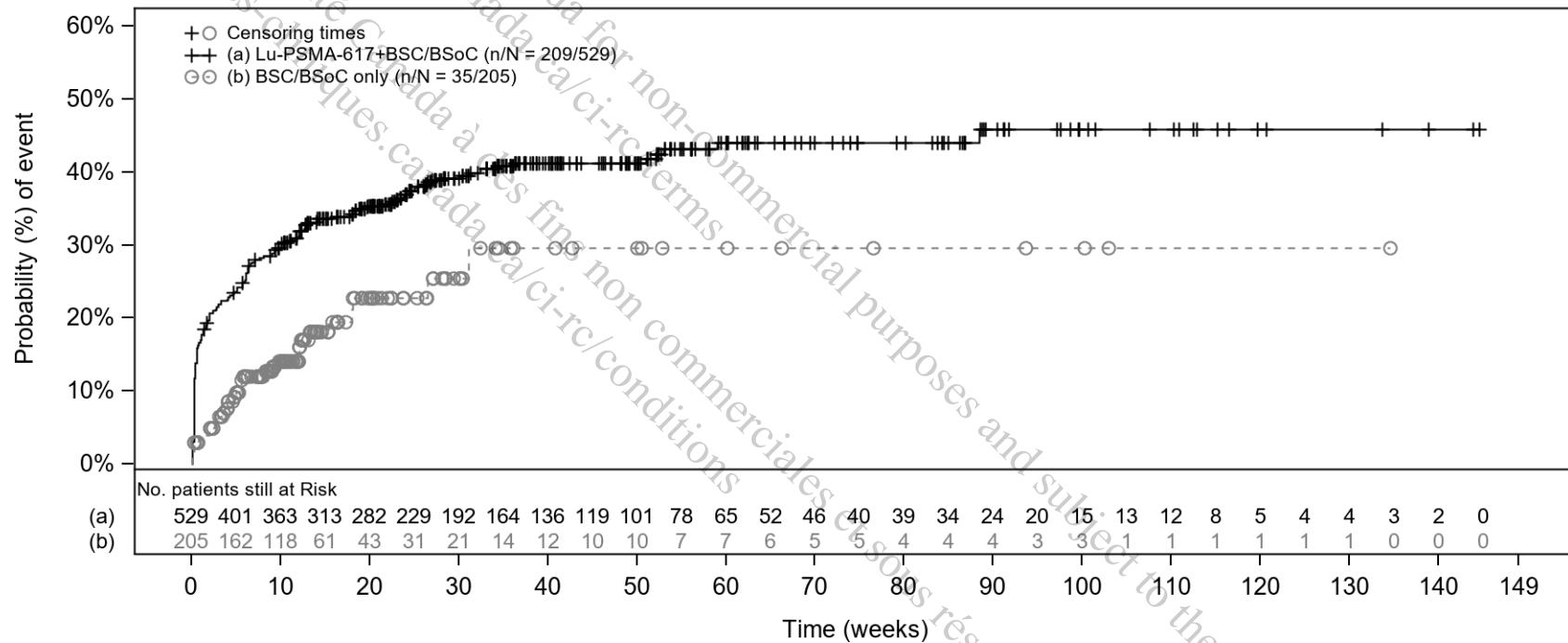
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Data Cutoff Date: 28JUN2021

Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)

Nausea and Vomiting



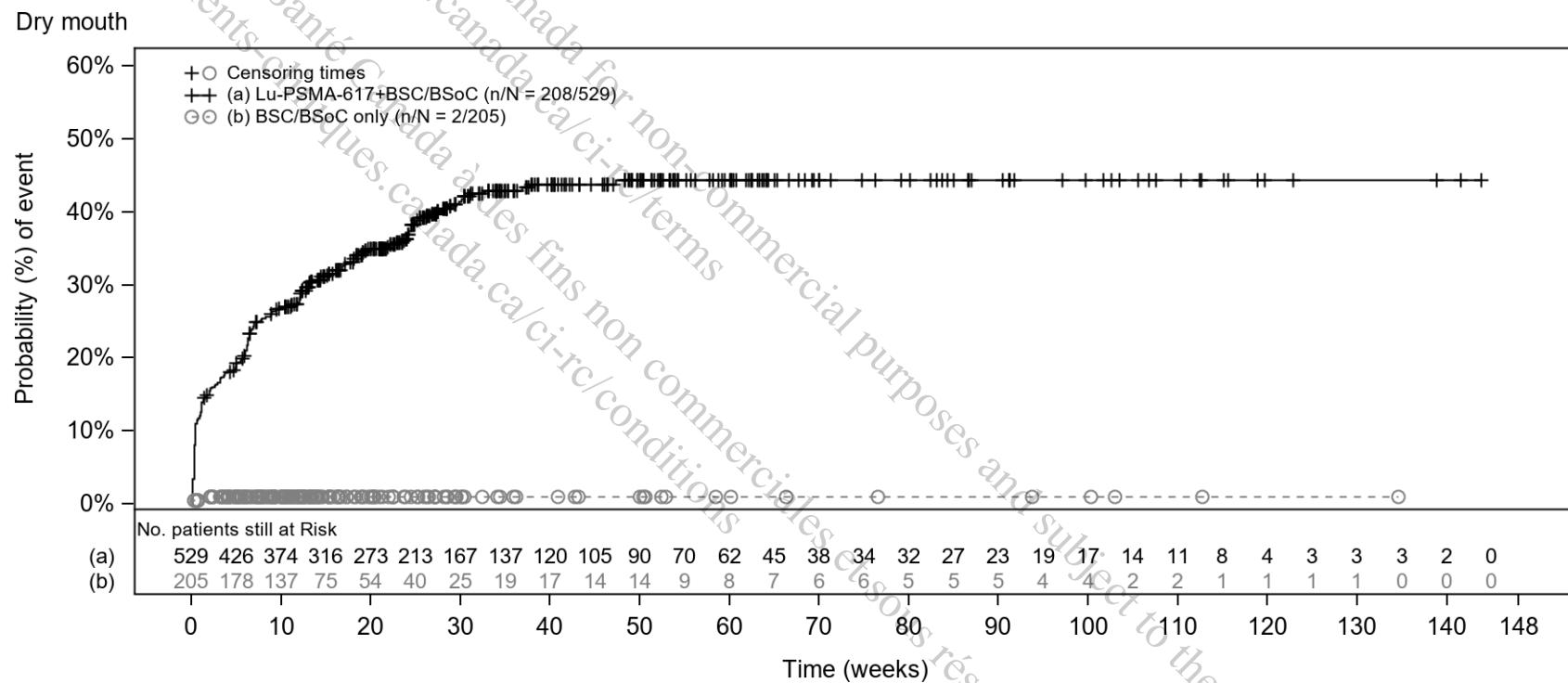
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Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



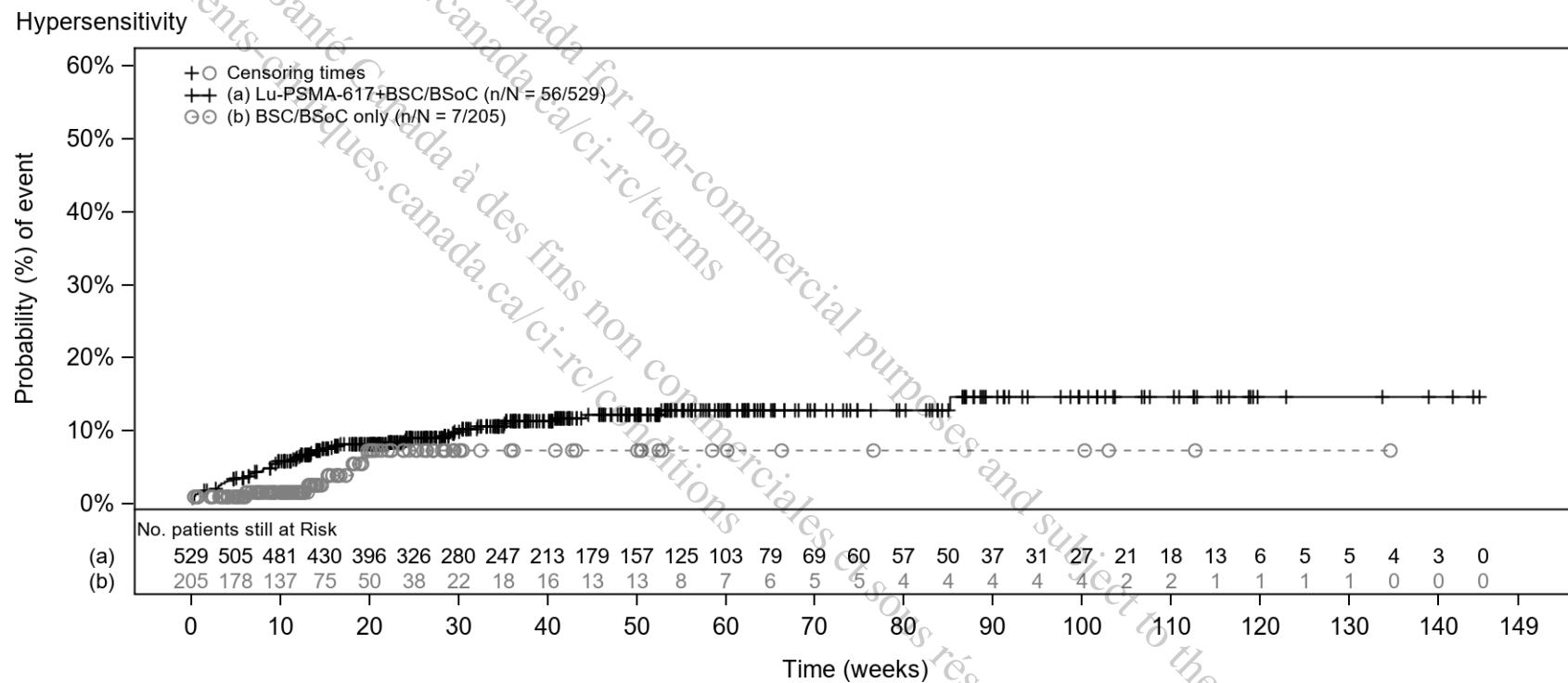
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Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



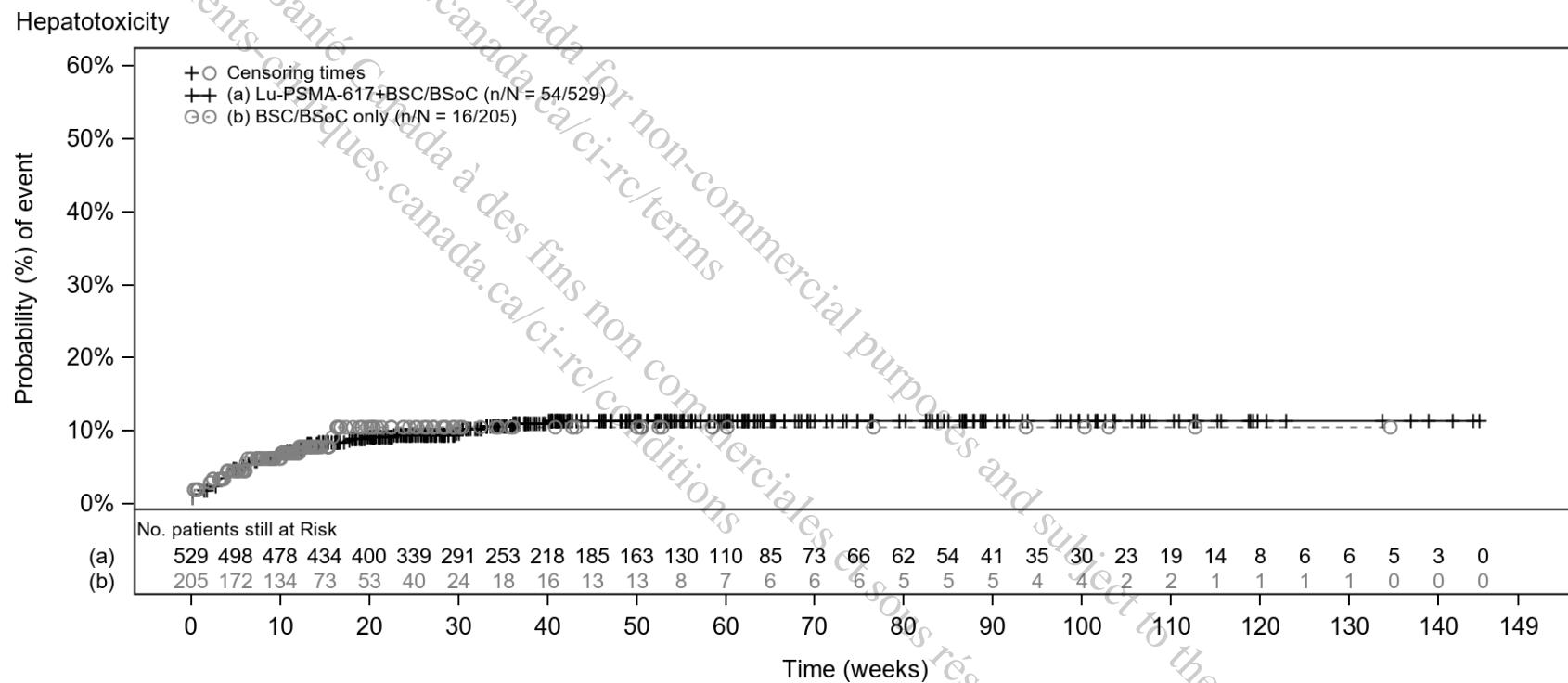
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Data Cutoff Date: 28JUN2021

Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



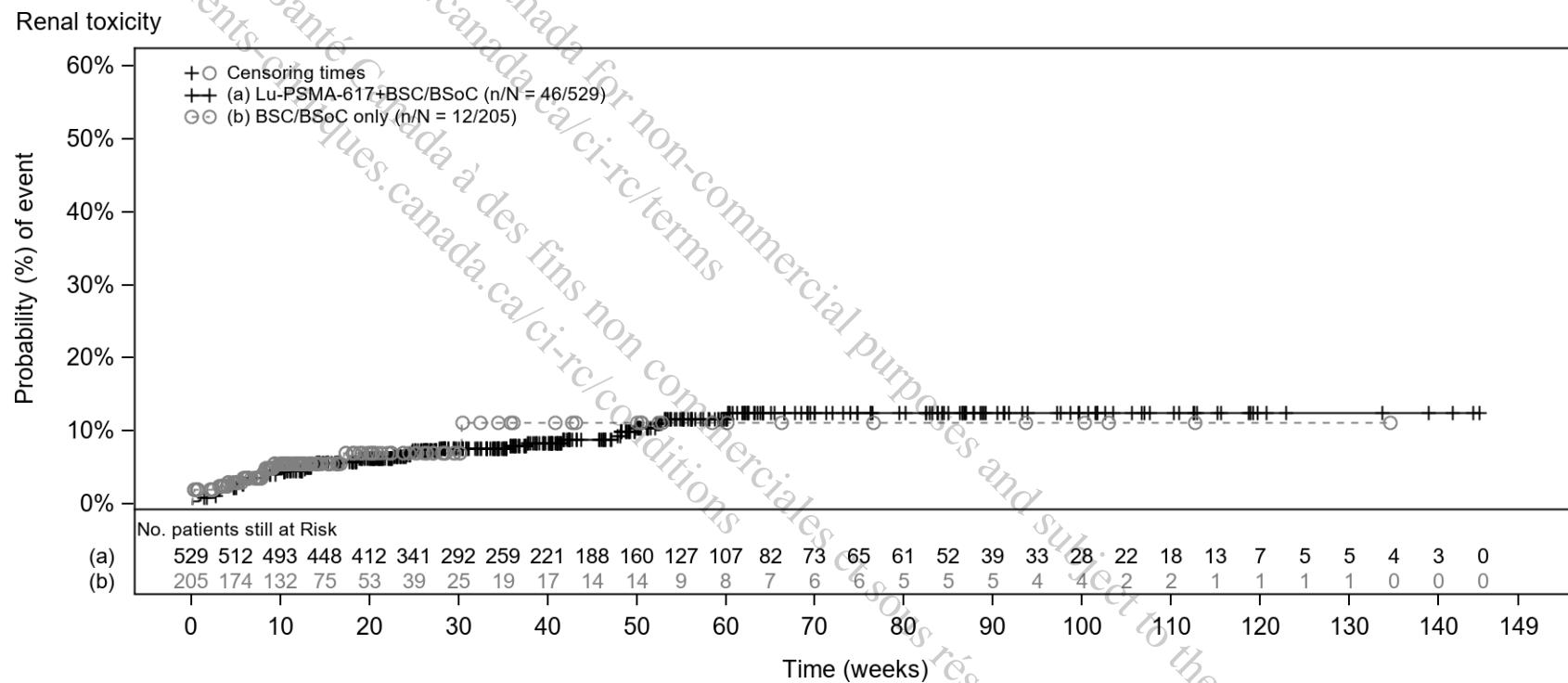
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Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



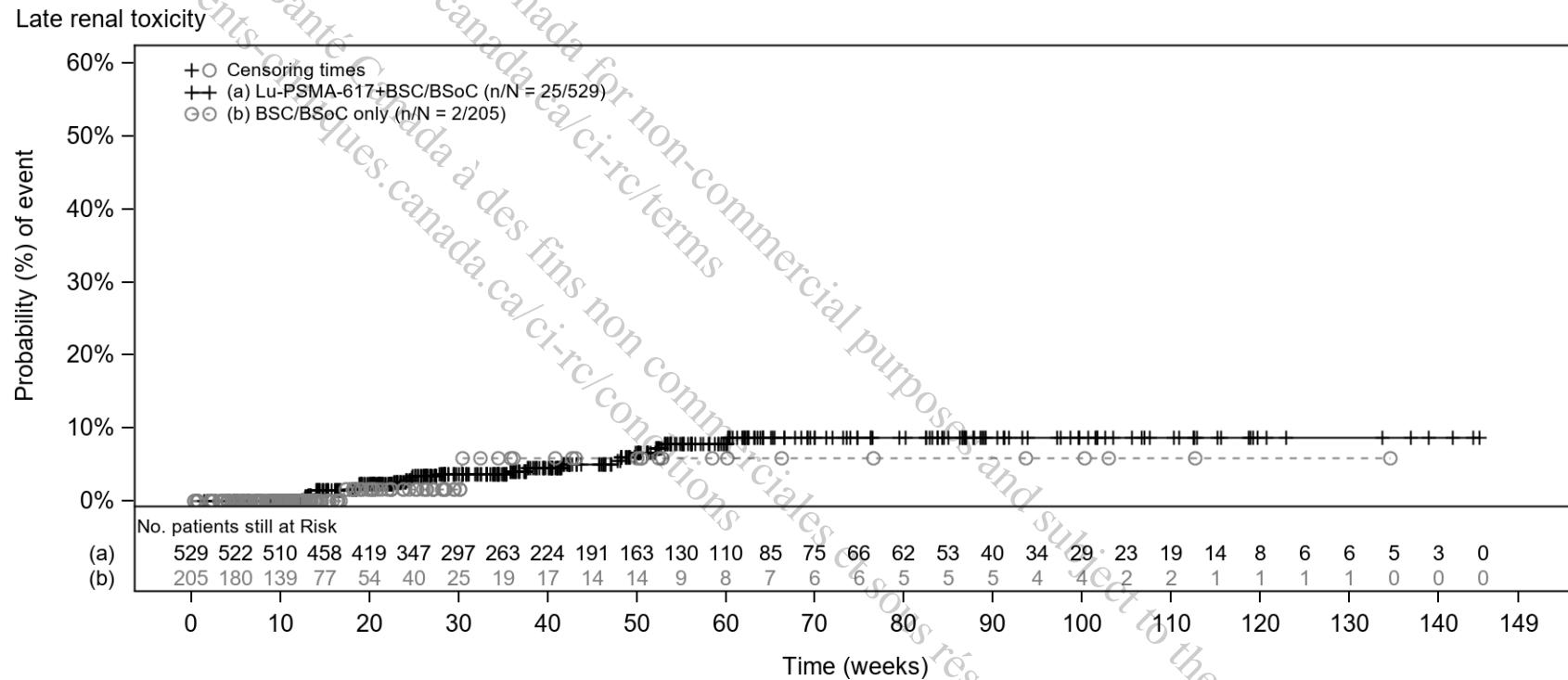
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Data Cutoff Date: 28JUN2021

Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



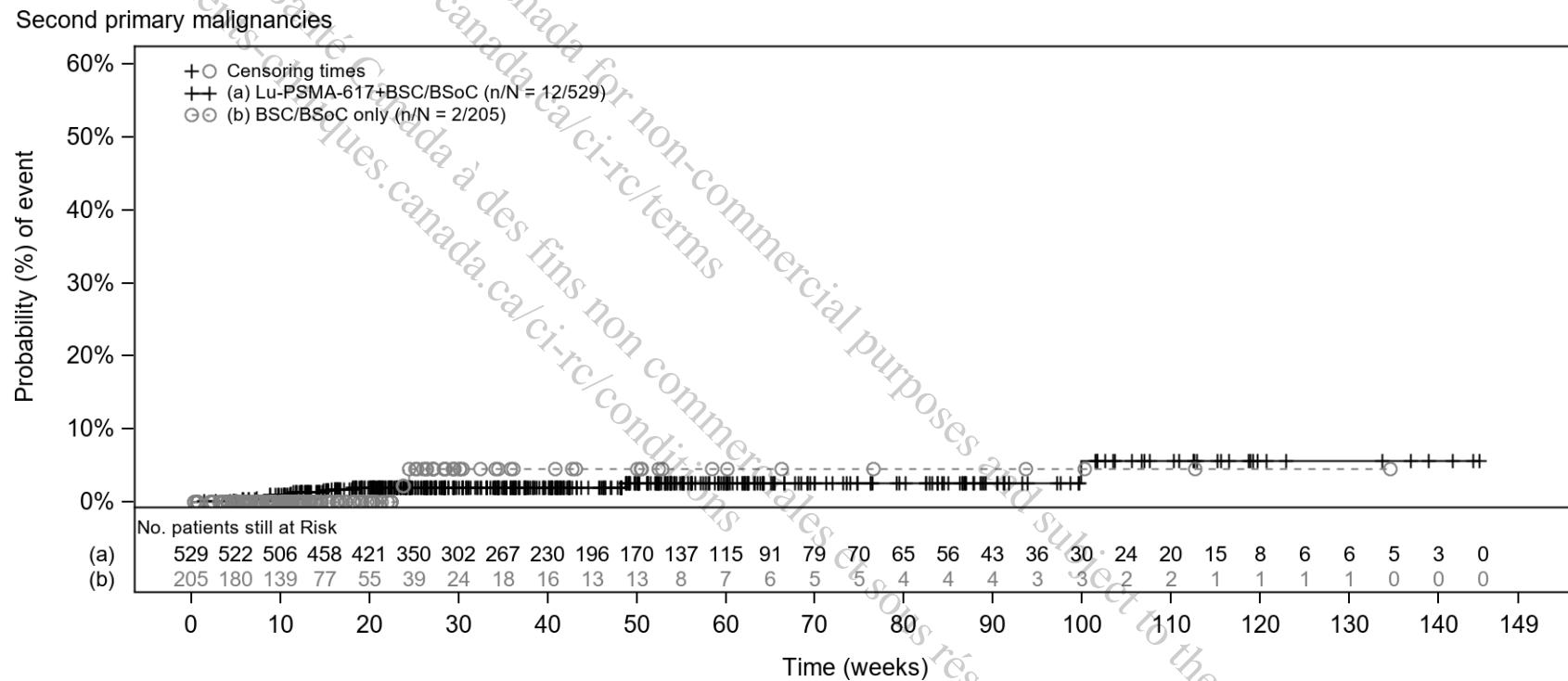
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Data Cutoff Date: 28JUN2021

Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



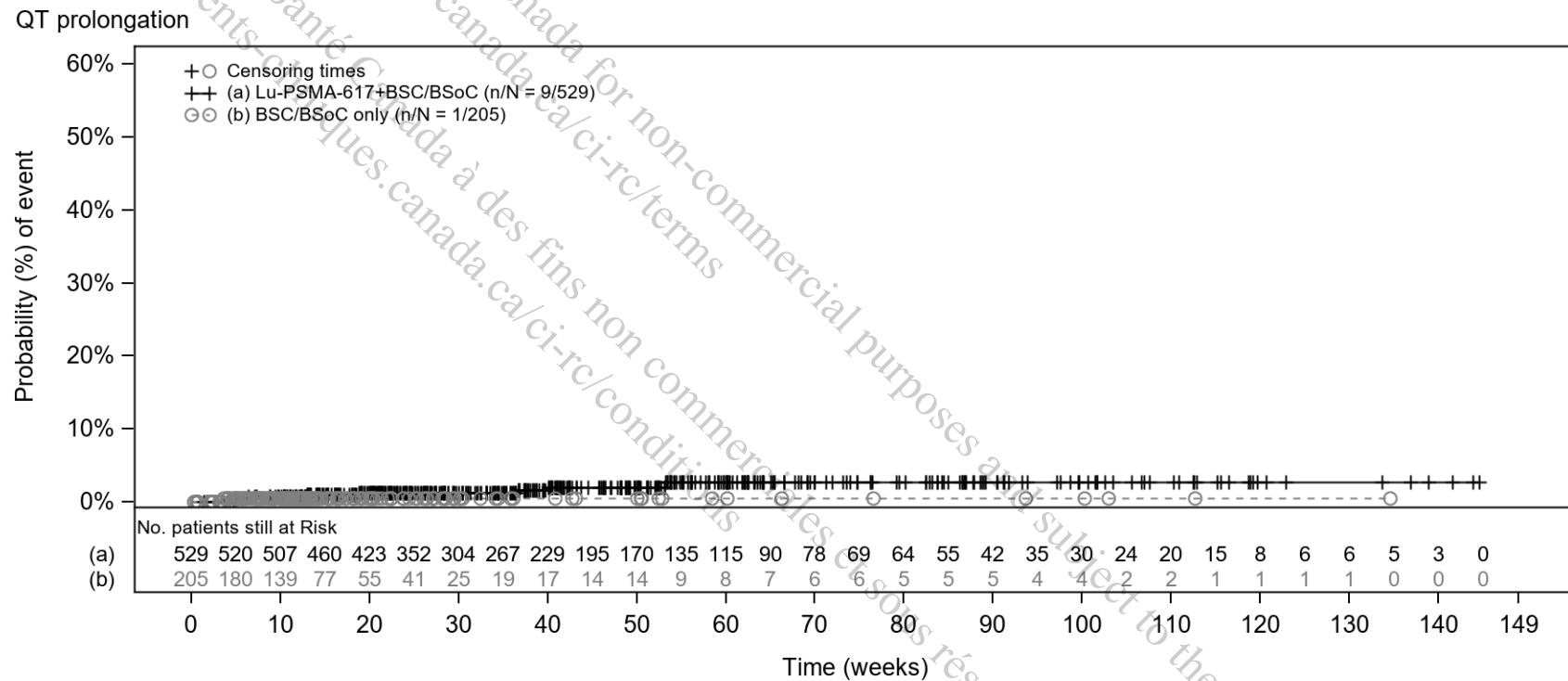
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Source data: adsl.xpt, adtte.xpt

Data Cutoff Date: 28JUN2021

Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



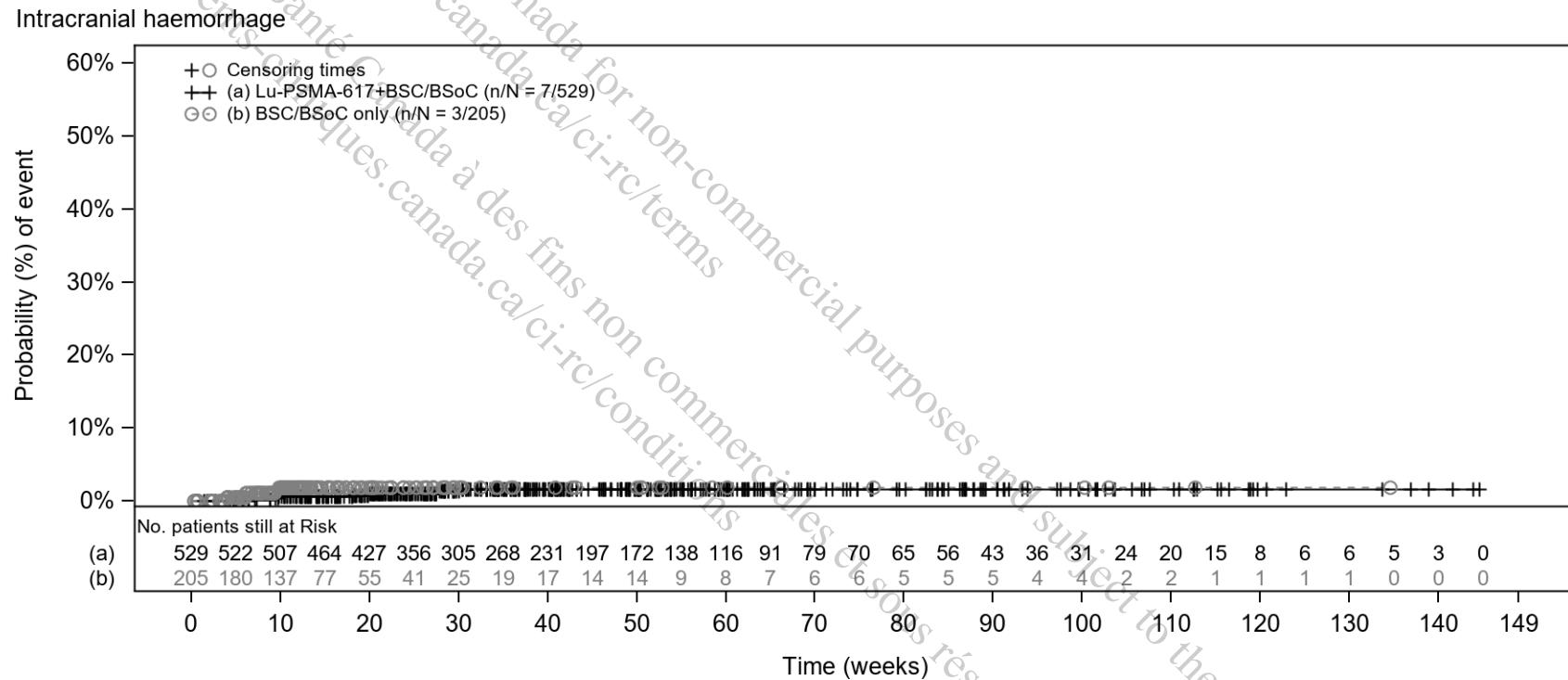
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Data Cutoff Date: 28JUN2021

Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



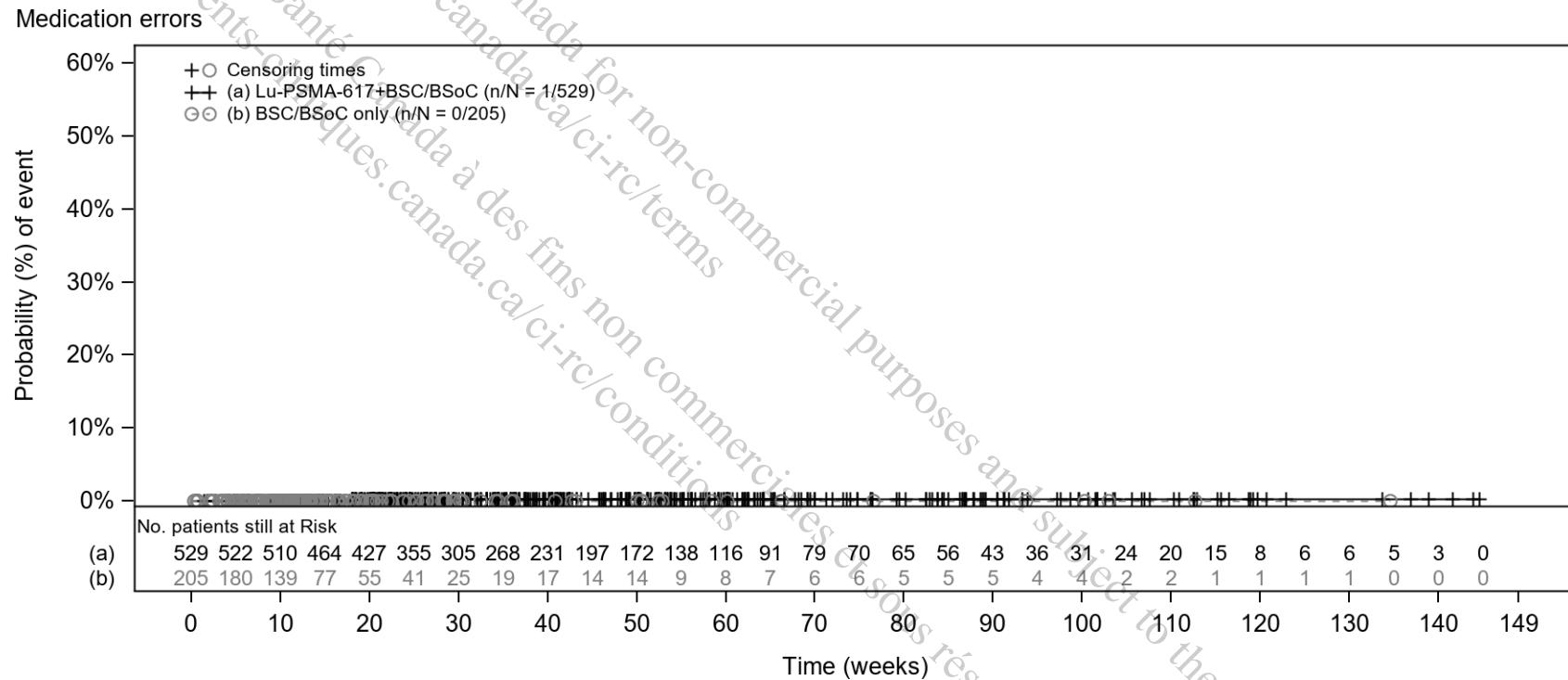
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Data Cutoff Date: 28JUN2021

Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



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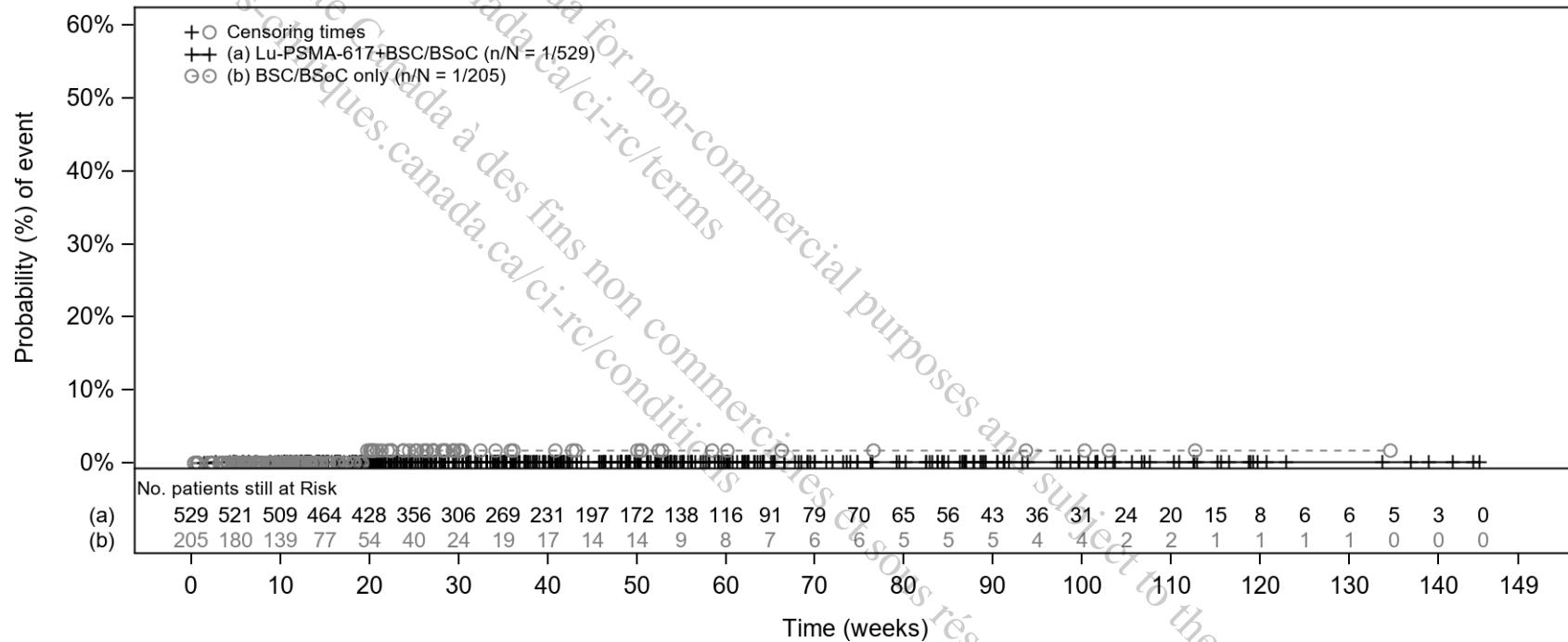
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Source data: adsl.xpt, adtte.xpt

Data Cutoff Date: 28JUN2021

Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)

Radiotoxicity including inadvertent exposure



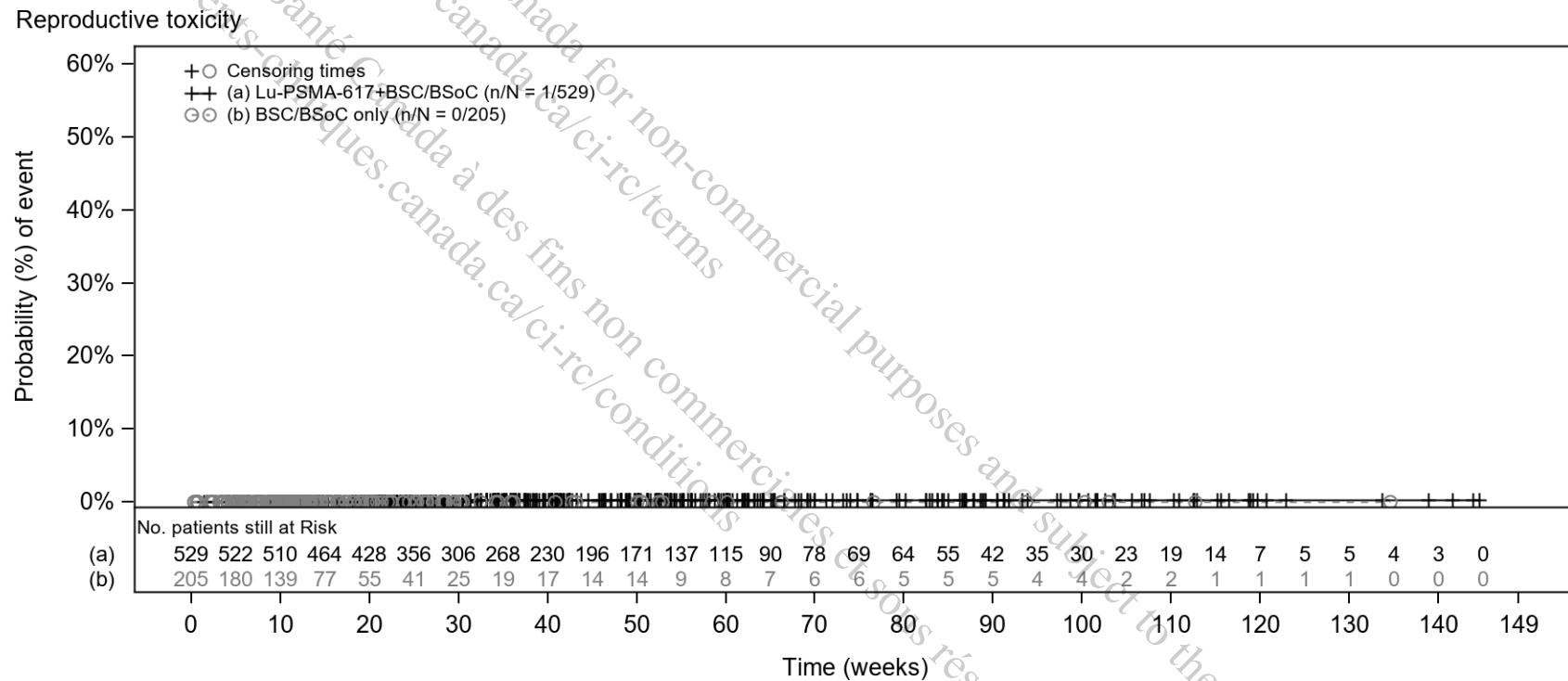
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Figure 2-1-5-1 Time to first occurrence of safety topic of interest (FAS safety set)



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**Pages 767 to 24072 of CSR Appendix 16.2
were removed due to being Out of Scope
as per Health Canada Guidance on Public
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