nced Accelerator Applications a Novartis Company						
nced Accelerator Applications, a Novartis Company A-617-01 Health Canada Table 8.12.8a Incidence of randomized tre	eatment-emergent adver	se drug reactio		Final Version	Safety Set)	
Table 0.12.04 molecules of fairhornized the		Lu-PSMA-617				
C2 02 00 00		+BSC/BSoC		E	SC/BSoC only	У
The this character	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderat (N=31) n (%)
ADR Fatigue	102	(757	(,,,	(,,,	11 (72)	11 (73)
Number of patients with at least one event Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Treatment-related AEs SAEs Action taken with PSMA-617	100 (43.7)	96 (41.9)	32 (46.4)	19 (24.4)	18 (18.9)	10 (32.3
Maximum grade	Ch Th					
Grade 3 AEs	15 (6.6)	12 (5.2)	4 (5.8)	0	0	3 (9.7)
Grade 4 AEs	o C,	· Ò ´	O	0	0	O
Grade 5 AEs	0	2/ 0	0	0	0	0
Treatment-related AEs	75 (32.8)	70 (30.6)	20 (29.0)	6 (7.7)	5 (5.3)	3 (9.7)
SAEs	1 (0.4)	0	1 (1.4)	0	0	0
Action taken with PSMA-617	17. 6	0	22			
Drug withdrawn	2 (0.9)	0	0/0	0	0	0
Dose reduced	1 (0.4)	1 (0.4)	0	0	0	0
Drug interrupted	0	O O	1 (1.4)	0	0	0
Dose not changed/NA/unknown	98 (42.8)	96 (41.9)	32 (46.4)	19 (24.4)	18 (18.9)	10 (32.3
Action taken with BSC/BSoC		000		X		
Drug withdrawn	3 (1.3)	2 (0.9)	0	×>0	0	0
Dose reduced	4 (1.7)	4 (1.7)	0	1 (1.3)	1 (1.1)	0
Drug interrupted	1 (0.4)	0	1 (1.4)	0	0	1 (3.2)
Dose not changed/NA/unknown	93 (40.6)	92 (40.2)	31 (44.9)	18 (23.1)	17 (17.9)	9 (29.0
AE outcome			0/0		20	
Recovered/resolved	36 (15.7)	30 (13.1)	9 (13.0)	0	3 (3.2)	1 (3.2)
Recovering/resolving	2 (0.9)	2 (0.9)	1 (1.4)	1 (1.3)	0	1 (3.2
Not recovered/not resolved	70 (30.6)	68 (29.7)	23 (33.3)	18 (23.1)	17 (17.9)	8 (25.8
Recovered/resolved with seguelae	0	0 (23.7)	0	0	0	0 (20.0
		-			-	
Fatal	0	0	0	0	0	0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR

Subgroups with at least 10 patients are presented

Subgroups with at least 10 patients are presented
Output ID: T-8-12-8a 2022-07-12 17:30
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Data Cutoff Date: 27JAN2021

anced Accelerator Applications, a Novartis Company						
A-617-01 Health Canada	d treetment emergent adva	roo drug roostic		Final Version	C Sofoty Sot)	
Table 8.12.8a Incidence of randomized		Lu-PSMA-617		GFK level (FAS		
10 02 10 4h		+BSC/BSoC		Е	SC/BSoC only	y
Alls Alice Alada	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Modera (N=31 n (%)
ADR Dry mouth	20. 10x		(70)	(70)		
Number of patients with at least one event	83 (36.2) 0 0 0 79 (34.5) 0 1 (0.4) 1 (0.4) 0	95 (41.5)	30 (43.5)	0	0	1 (3.2
Maximum grade	Ch Th					
Grade 3 AEs		0	0	0	0	0
Grade 4 AEs	0 0	0	0	0	0	0
Grade 5 AEs	, 20, 0	2/ 0	0	0	0	0
Treatment-related AEs	79 (34.5)	86 (37.6)	28 (40.6)	0	0	0
SAEs	CONTRIBO	0 %	0	0	0	0
Action taken with PSMA-617	17. 6	0	92			
Drug withdrawn	1 (0.4)	0	0	0	0	0
Dose reduced	1 (0.4)	0	2 (2.9)	0	0	0
Drug interrupted	0	0	0%.	0	0	0
Dose not changed/NA/unknown	81 (35.4)	95 (41.5)	29 (42.0)	0	0	1 (3.2
Action taken with BSC/BSoC		U.S.		6		
Drug withdrawn	1 (0.4)	0	0	ZZ0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	82 (35.8)	95 (41.5)	30 (43.5)	0 0	0	1 (3.2
AE outcome			C 0		Zs.	
Recovered/resolved	30 (13.1)	35 (15.3)	5 (7.2)	0	0×0	1 (3.2
Recovering/resolving	4 (1.7)	2 (0.9)	2 (2.9)	0	0	0
Not recovered/not resolved	49 (21.4)	63 (27.5)	26 (37.7)	0	00	1 (3.2
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0 2 (0.9)	0 2 (0.9)	0 0	.00	0	0 0
Unknown	2 (0 0)				0	

Final Version

		Lu-PSMA-617					
_		+BSC/BSoC		BSC/BSoC only			
-	Normal	Mild	Moderate	Normal	Mild	Moderate	
	(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR

Subgroups with at least 10 patients are presented

Subgroups with at least 10 patients are presented
Output ID: T-8-12-8a 2022-07-12 17:30
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Data Cutoff Date: 27JAN2021

anced Accelerator Applications, a Novartis Company						
A-617-01 Health Canada				Final Version		
Table 8.12.8a Incidence of randomize	d treatment-emergent adver	Lu-PSMA-617				
Chis Co Canada	Normal (N=229) n (%)	+BSC/BSoC Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	SSC/BSoC only Mild (N=95) n (%)	y Moder (N=3 n (%
ADR Nausea	ac, hop					
Number of patients with at least one event	76 (33.2)	82 (35.8)	28 (40.6)	12 (15.4)	14 (14.7)	8 (25.
Maximum grade Grade 3 AEs	76 (33.2) 4 (1.7) 0 0 60 (26.2) 1 (0.4)	2 (0.9)	1 (1.4)	1 (1.3)	0	0
Grade 4 AEs Grade 5 AEs		0	0 0	0 0	0 0	0
Treatment-related AEs	60 (26.2)	65 (28.4)	22 (31.9)	3 (3.8)	3 (3.2)	2 (6.5
SAEs	1 (0.4)	1 (0.4)	1 (1.4)	1 (1.3)	0	0
Action taken with PSMA-617 Drug withdrawn	11/10 0 0 13 1	0	² 170/0	0	0	0
2000.000000		0	.0	0	0	0
Drug interrupted Dose not changed/NA/unknown	0 76 (33.2)	0 82 (35.8)	0 28 (40.6)	0 12 (15.4)	0 14 (14.7)	0 8 (25.8
-	70 (33.2)	(00.0)	20 (40.0)	12 (10. 7)	17 (1 7. 1)	0 (20.0
Action taken with BSC/BSoC	0		0	1,(1.3)	0	0
Drug withdrawn Dose reduced	0	1 (0.4)	. 0 > 0	1 (1.3)	0 0	0 0
Drug interrupted	1 (0.4)	2 (0.9)	<u>0</u> 0	0	1 (1.1)	0
Dose not changed/NA/unknown	76 (33.2)	80 (34.9)	28 (40.6)	10 (12.8)	13 (13.7)	8 (25.8
AE outcome			900		Sr.	
Recovered/resolved	46 (20.1)	57 (24.9)	20 (29.0)	6 (7.7)	9 (9.5)	3 (9.7
Recovering/resolving	1 (0.4)	1 (0.4)	1 (1.4)	1 (1.3)	0	0
Not recovered/not resolved Recovered/resolved with sequelae	32 (14.0) 1 (0.4)	31 (13.5) 0	8 (11.6) 0	7 (9.0) 0	6 (6.3) 0	5 (16. ²
Fatal	0 (0.4)	0	0	0	0	0
Unknown	1 (0.4)	1 (0.4)	Ö	0	0	0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR

Subgroups with at least 10 patients are presented

eGPR Categliories all easit 10 patients are presented.

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anced Accelerator Applications a Novartis Company						
anced Accelerator Applications, a Novartis Company A-617-01 Health Canada Table 8.12.8a Incidence of randomize	ed treatment-emergent adver	se drug reactio		Final Version	Safety Set)	
The state of the s		Lu-PSMA-617				
Ch dr Ca th	9	+BSC/BSoC			SC/BSoC onl	
The street of th	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Modera (N=3° n (%
ADR Anaemia	a C. to					
Number of patients with at least one event	68 (29.7) 31 (13.5) 1 (0.4) 0 57 (24.9) 8 (3.5)	77 (33.6)	22 (31.9)	12 (15.4)	8 (8.4)	7 (22.0
Maximum grade						
Grade 3 ĀEs	31 (13.5)	28 (12.2)	7 (10.1)	4 (5.1)	3 (3.2)	3 (9.7
Grade 4 AEs	1 (0.4)	1 (0.4)	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	57 (24.9)	61 (26.6)	16 (23.2)	2 (2.6)	1 (1.1)	3 (9.7
SAEs	8 (3.5)	5 (2.2)	2 (2.9)	0	1 (1.1)	0
Action taken with PSMA-617	V/2. C.	J	92			
Drug withdrawn	5 (2.2)	8 (3.5)	2 (2.9)	0	0	1 (3.2
Dose reduced	3 (1.3)	2 (0.9)	2 (2.9)	0	0	0
Drug interrupted	6 (2.6)	16 (7.0)	5 (7.2)	0	0	1 (3.2
Dose not changed/NA/unknown	63 (27.5)	66 (28.8)	21 (30.4)	12 (15.4)	8 (8.4)	6 (19.
Action taken with BSC/BSoC		040		6		
Drug withdrawn	2 (0.9)	2 (0.9)	1 (1.4)	×>0	0	0
Dose reduced	0	0 8	0	6	0	0
Drug interrupted	2 (0.9)	4 (1.7)	3 (4.3)	0	0	0
Dose not changed/NA/unknown	66 (28.8)	73 (31.9)	21 (30.4)	12 (15.4)	8 (8.4)	7 (22.0
AE outcome			900	*17	S	
Recovered/resolved	21 (9.2)	22 (9.6)	11 (15.9)	5 (6.4)	2 (2.1)	3 (9.7
Recovering/resolving	1 (0.4)	Ò ,	0 0,	0	0	1 (3.2
Not recovered/not resolved	51 (22.3)	58 (25.3)	15 (21.7)	8 (10.3)	6 (6.3)	4 (12.9
Recovered/resolved with sequelae	O ,	1 (0.4)	O ,	75.0	0	[°] 0
Fatal	0	0	0	00	0	0
Unknown	0	0	0	1.60	0	0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR eOFR Categlyines all east 10 patients are presented.
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anced Accelerator Applications, a Novartis Company A-617-01 Health Canada				Final Version	Cafathy Cat)	
Table 8.12.8a Incidence of randomized trea		Lu-PSMA-617		GFR level (FAS		
102 03 1.C. 40		+BSC/BSoC		BS	SC/BSoC only	У
The this contacts	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Modera (N=31 n (%)
ADR Decreased appetite	. Po.					
Number of patients with at least one event	31 (13.5) 0 31 (13.5)	42 (18.3)	23 (33.3)	17 (21.8)	9 (9.5)	4 (12.9
Maximum grade	Ch Ch					
Grade 3 AEs	5 (2.2)	4 (1.7)	0	1 (1.3)	0	0
Grade 4 AEs	0 °C,	1 (0.4)	0	0	0	0
Grade 5 AEs	0	2/ 0	0	0	0	0
Treatment-related AEs	31 (13.5)	25 (10.9)	11 (15.9)	4 (5.1)	1 (1.1)	1 (3.2
SAEs	CONTINUO	000	1 (1.4)	0	0	0
Action taken with PSMA-617	17. 6	0	92			
Drug withdrawn	0, 0/2,	0	0/0	0	0	0
Dose reduced	\$ 0 °C	0	0	0	0	0
Drug interrupted	1 (0.4)	0	0%.	0	0	0
Dose not changed/NA/unknown	45 (19.7)	42 (18.3)	23 (33.3)	17 (21.8)	9 (9.5)	4 (12.9
Action taken with BSC/BSoC		000		7		
Drug withdrawn	1 (0.4)	0	1 (1.4)	×>0	0	0
Dose reduced	0	0 0) 0	1 (1.3)	Ö	0
Drug interrupted	0	0	C ₂ 0	0	0	0
Dose not changed/NA/unknown	45 (19.7)	42 (18.3)	22 (31.9)	16 (20.5)	9 (9.5)	4 (12.9
AE outcome			0/0		ſ.	
Recovered/resolved	19 (8.3)	17 (7.4)	8 (11.6)	3 (3.8)	2 (2.1)	3 (9.7
Recovering/resolving	3 (1.3)	1 (0.4)	3 (4.3)	0	0	0
Not recovered/not resolved	29 (12.7)	28 (12.2)	12 (17.4)	14 (17.9)	7 (7.4)	1 (3.2
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	Ö	00	Ö	Ö
Unknown	0	0	0	00	0	0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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n-617-01 Health Canada Table 8.12.8a Incidence of randomized t	reatment-emergent adve			Final Version		
102 42	realment emergent dave	rse drug reactio	ns by baseline e	GFR level (FAS	Safety Set)	
The Sold of the sales	.	Lu-PSMA-617 +BSC/BSoC		E	BSC/BSoC only	v
The Chief	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) n (%)
ADR Constipation	Or Por					
Number of patients with at least one event	41 (17.9)	50 (21.8)	16 (23.2)	7 (9.0)	10 (10.5)	6 (19.4)
Maximum grade	Chy thin	- ()	- 41			
Grade 3 AEs	1 (0.4)	2 (0.9)	2 (2.9)	0	0	1 (3.2)
Grade 4 AEs Grade 5 AEs	, O C	1 (0.4)	0 0	0 0	0 0	0 0
Treatment-related AEs	1 (0.4) 0 0 19 (8.3) 1 (0.4)	21 (9.2)	5 (7.2)	0	0	1 (3.2)
SAEs	(0.4)	2 (0.9)	2 (2.9)	0	0	1 (3.2)
Action taken with PSMA-617	Viz. Cr	0	92			
Diag williami	0,000	0	0	0	0	0
Dose reduced	10 0 C	0	0	0	0	0
Drug interrupted Dose not changed/NA/unknown	0 41 (17.9)	0 50 (21.8)	1 (1.4) 15 (21.7)	0 7 (9.0)	0 10 (10.5)	0 6 (19.4)
Action taken with BSC/BSoC		Ollo		6		
Drug withdrawn	0	0	0	2%0	0	0
Dose reduced	0	0	0	0	0 0	0
Drug interrupted Dose not changed/NA/unknown	41 (17.9)	1 (0.4) 49 (21.4)	0 16 (23.2)	7 (9.0)	10 (10.5)	0 6 (19.4)
AE outcome			90	`?	Sr.	
Recovered/resolved	28 (12.2)	32 (14.0)	6 (8.7)	2 (2.6)	(1.1)	4 (12.9)
Recovering/resolving	1 (0.4)	1 (0.4)	2 (2.9)	1 (1.3)	0	0
Not recovered/not resolved Recovered/resolved with sequelae	17 (7.4)	22 (9.6)	10 (14.5)	5 (6.4)	9 (9.5)	3 (9.7)

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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Action taken with PSMA-617 Drug withdrawn Dru	only Modera (N=31 n (%)
Lu-PSMA-617	only Modera (N=31 n (%)
Normal (N=229)	Modera (N=31 n (%)
ADR Leukopenia Number of patients with at least one event 41 (17.9) 32 (14.0) 9 (13.0) 1 (1.3) 3 (3.2) Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Grade 5 AEs Grade 5 AEs Grade 6 AEs Grade 6 AEs Grade 7 AEs Grade 7 AEs Grade 8 (3.5) 6 (2.6) 3 (4.3) 0 1 (1.1) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	0
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	0
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	0
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	0
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	0
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	0
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	0
Dose not changed/NA/unknown 39 (17.0) 30 (13.1) 8 (11.6) 1 (1.3) 3 (3.2 Action taken with BSC/BSoC	0
Action taken with BSC/BSoC	0
	0
1/1/0/9/11/0/9/11	0
Dose reduced 0 0 0 0 0	0
Drug interrupted 1 (0.4) 0 0 0 0	0
Dose not changed/NA/unknown 40 (17.5) 32 (14.0) 9 (13.0) 1 (1.3) 3 (3.2)	
AE outcome	
Recovered/resolved 29 (12.7) 21 (9.2) 8 (11.6) 1 (1.3) 0	0
Recovering/resolving 2 (0.9) 0 0 0 0	0
Not recovered/not resolved 16 (7.0) 15 (6.6) 2 (2.9) 0 3 (3.2)	N) -
Recovered/resolved with sequelae 0 1 (0.4) 0 0	0
Fatal 0 0 0 0 0 Unknown 0 0 0 0 0	
UTIKITUWIT U U U U U U	0 0

Final Version

	Lu-PSMA-617				
	+BSC/BSoC		E	BSC/BSoC onl	у
Normal	Mild	Moderate	Normal	Mild	Moderate
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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A-617-01 Health Canada Table 8.12.8a Incidence of randomized trea	atmost amargant adva			Final Version				
	aimeni-emergeni adve	tment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)						
the South of the	.	Lu-PSMA-617 +BSC/BSoC		В:	SC/BSoC only	v		
TIES CITE CO TOTAL TO THE TOTAL	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) n (%)		
ADR Diarrhea	· 402							
Number of patients with at least one event	40 (17.5)	40 (17.5)	19 (27.5)	2 (2.6)	2 (2.1)	2 (6.5)		
Maximum grade	Ch Mh							
Grade 3 AEs	1 (0.4)	1 (0.4)	2 (2.9)	1 (1.3)	0	0		
Grade 4 AEs	0 0	0	0	0	0	0		
Grade 5 AEs	0	2/0	0	0	0	0		
Treatment-related AEs	21 (9.2)	25 (10.9)	11 (15.9)	0	0	0		
Number of patients with at least one event Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Treatment-related AEs SAEs Action taken with PSMA-617 Drug withdrawn Dose reduced	0/2 17/1/20	0	0	1 (1.3)	0	0		
Action taken with PSMA-617	Viz. Cr	-0	, 2.					
Drug withdrawn	0,000	0	·200	0	0	0		
2000.000000	0 0	0	0	0	0	0		
Drug interrupted	0 (47.5)	1 (0.4) 40 (17.5)	1 (1.4)	0	0	0		
Dose not changed/NA/unknown	40 (17.5)	40 (17.5)	19 (27.5)	2 (2.6)	2 (2.1)	2 (6.5)		
Action taken with BSC/BSoC		V.		6				
Drug withdrawn	0	1 (0.4)	0	ZZ0	0	0		
Dose reduced	0	0	0	0	0	0		
Drug interrupted Dose not changed/NA/unknown	1 (0.4) 39 (17.0)	1 (0.4) 39 (17.0)	0 19 (27.5)	0 2 (2.6)	0 2 (2.1)	0 2 (6.5)		
bose not changed/NA/unknown	39 (17.0)	39 (17.0)	19 (27.5)	2 (2.0)	2 (2.1)	2 (0.5)		
AE outcome			00		S _			
Recovered/resolved	33 (14.4)	29 (12.7)	15 (21.7)	1 (1.3)	2 (2.1)	2 (6.5)		
Recovering/resolving	2 (0.9)	1 (0.4)	0	0	0	0		
				∀/ √ _	000	0		
Not recovered/not resolved Recovered/resolved with sequelae	6 (2.6) 0	12 (5.2) 0	7 (10.1) 0	1 (1.3) 0	0	C		
Fatal Unknown	0 0	0 0	0	0	0	0		

Final Version

	Lu-PSMA-617				
	+BSC/BSoC			BSC/BSoC onl	у
Normal	Mild	Moderate	Normal	Mild	Moderate
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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A-617-01 Health Canada				Final Version		
Table 8.12.8a Incidence of randomize	ed treatment-emergent adver			GFR level (FA	S Safety Set)	
The Committee of the Co		Lu-PSMA-617 +BSC/BSoC		ı	BSC/BSoC only	.,
This drift Carada	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Modera (N=31 n (%)
ADR Thrombocytopenia	20.20	(76)	(79)	(70)	(70)	
Number of patients with at least one event	40 (17.5)	39 (17.0)	11 (15.9)	5 (6.4)	3 (3.2)	1 (3.2)
Maximum grade	Ch th					
Grade 3 AEs	13 (5.7)	13 (5.7)	4 (5.8)	1 (1.3)	1 (1.1)	0
Grade 4 AEs	6 (2.6) C	5 (2.2)	0	0	0	0
Grade 5 AEs	0	2/ 0	0	0	0	0
Treatment-related AEs	36 (15.7)	35 (15.3)	11 (15.9)	0	0	0
SAEs	40 (17.5) 13 (5.7) 6 (2.6) 0 36 (15.7) 1 (0.4)	2 (0.9)	0	0	0	0
Action taken with PSMA-617	47. 60.	0	92			
Drug withdrawn	5 (2.2)	7 (3.1)	3 (4.3)	0	0	0
Dose reduced	4 (1.7)	4 (1.7)	2 (2.9)	0	0	0
Drug interrupted Dose not changed/NA/unknown	5 (2.2) 37 (16.2)	10 (4.4) 32 (14.0)	3 (4.3) 9 (13.0)	0 5 (6.4)	0 3 (3.2)	1 (3.2)
Dose not changed/NA/unknown	31 (10.2)	32 (14.0)	9 (13.0)	5 (0.4)	3 (3.2)	1 (3.2)
Action taken with BSC/BSoC		40	~	6		
Drug withdrawn	3 (1.3)	1 (0.4)	1 (1.4)	Z ₀ 0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted Dose not changed/NA/unknown	1 (0.4) 39 (17.0)	2 (0.9) 38 (16.6)	0 11 (15.9)	0 5 (6.4)	0 3 (3.2)	0 1 (3.2)
Dose not changed/NA/dilknown	39 (17.0)	30 (10.0)	10 (13.9)	J (U.4)C	5 (3.2)	1 (3.2)
AE outcome			, Co		S	
Recovered/resolved	10 (4.4)	10 (4.4)	5 (7.2)	1 (1.3)	0	0
Recovering/resolving Not recovered/not resolved	1 (0.4)	0 31 (13 5)	0 0	0	0 3 (3.2)	0
Recovered/resolved with sequelae	32 (14.0) 0	31 (13.5) 0	8 (11.6) 0	4 (5.1) 0	ა (ა.∠) ი	1 (3.2) 0
Fatal	0	0	0	0.0	0	0
Unknown	0	0	1 (1.4)	0	0	0
				0/3		Pan

Final Version

	Lu-PSMA-617				
	+BSC/BSoC			BSC/BSoC onl	у
Normal	Mild	Moderate	Normal	Mild	Moderate
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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A-617-01 Health Canada Table 8.12.8a Incidence of randomized tr				Final Version		
	eatment-emergent adve	rse drug reaction	ons by baseline e	GFR level (FAS	Safety Set)	
The S. P. O. A.		Lu-PSMA-617 +BSC/BSoC		B	SC/BSoC onl	V
Tits, difference analyda	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) n (%)
ADR Vomiting	2. 702					
Number of patients with at least one event	38 (16.6)	45 (19.7)	17 (24.6)	5 (6.4)	5 (5.3)	3 (9.7)
Maximum grade	Chy thin					
Grade 3 AEs	2 (0.9)	2 (0.9)	1 (1.4)	1 (1.3)	0	0
Grade 4 AEs Grade 5 AEs	0 0	· 0	0 0	0 0	0 0	0 0
Crado o Aleo	0	A	-	-		Ü
Treatment-related AEs	21 (9.2)	25 (10.9)	16 (23.2)	2 (2.6)	1 (1.1)	0
Number of patients with at least one event Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Treatment-related AEs SAEs	3 (1.3)	1 (0.4)	1 (1.4)	1 (1.3)	0	0
Action taken with PSMA-617	~/ X · ~/^_	0	22			
Drug withdrawn	1 (0.4)	0	0	0	0	0
Dose reduced	10,0 16	0	0	0	0	0
Drug interrupted Dose not changed/NA/unknown	0 37 (16.2)	0 45 (19.7)	17 (24.6)	0 5 (6.4)	0 5 (5.3)	0 3 (9.7)
	o. (.o. <u>_</u>)	50	(=)	(0.1)	0 (0.0)	0 (0)
Action taken with BSC/BSoC	•		0	6	•	0
Drug withdrawn Dose reduced	0 0	1 (0.4)	. 0	30	0 0	0 0
Drug interrupted	1 (0.4)	0.4)	C ₂ 0	0	0	0
Dose not changed/NA/unknown	38 (16.6)	44 (19.2)	17 (24.6)	5 (6.4)	5 (5.3)	3 (9.7)
-			0/2		20	
AE outcome	00 (40 7)	05 (45 0)	45 (245)	4 (5.4)	(F (F 0)	0 (0 5)
Recovered/resolved Recovering/resolving	29 (12.7) 0	35 (15.3) 0	15 (21.7) 0	4 (5.1) 0	5 (5.3) 0	2 (6.5) 0
Not recovered/not resolved			-		0.0	-
Not recovered/not resolved Recovered/resolved with sequelae	12 (5.2) 1 (0.4)	13 (5.7) 0	3 (4.3) 0	1 (1.3) 0	0.00	1 (3.2) 0
Fatal Unknown	0	0	0	00	0	0

Final Version

	Lu-PSMA-617				
	+BSC/BSoC			BSC/BSoC onl	у
Normal	Mild	Moderate	Normal	Mild	Moderate
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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A-617-01 Health Canada Table 8.12.8a Incidence of randomized tre				Final Version		
	atment-emergent adve	rse drug reactio	ons by baseline e	GFR level (FAS	Safety Set)	
Charles Cap		Lu-PSMA-617 +BSC/BSoC		В	SC/BSoC only	v
The chief and day	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) n (%)
ADR Lymphopenia	, 70,			, ,		
Number of patients with at least one event	29 (12.7)	33 (14.4)	13 (18.8)	3 (3.8)	4 (4.2)	1 (3.2)
Maximum grade	Ch the		- 4>	_		_
Grade 3 AEs	17 (7.4)	14 (6.1)	6 (8.7)	0	1 (1.1)	0
Grade 4 AEs	2 (0.9)	2 (0.9)	0	0	0	0
Grade 5 AEs	0	8/ 0	0	0	0	0
Treatment-related AEs	25 (10.9)	26 (11.4)	10 (14.5)	1 (1.3)	1 (1.1)	0
SAEs	29 (12.7) 17 (7.4) 2 (0.9) 0 25 (10.9)	0	0	0	0	0
Action taken with PSMA-617	(1/2. C)	-0	2.			
Drug withdrawn	0, 0/2,	2 (0.9)	² / ₂ 0/0	0	0	0
Dose reduced	30 °C	1 (0.4)	1 (1.4)	0	0	0
Drug interrupted	0	1 (0.4)	0/6,.	0	0	0
Dose not changed/NA/unknown	29 (12.7)	32 (14.0)	12 (17.4)	3 (3.8)	4 (4.2)	1 (3.2)
Action taken with BSC/BSoC		00		Z		
Drug withdrawn	0	0	0	×>0	0	0
Dose reduced	0	0 8	0	Q 0	0	0
Drug interrupted	0	2 (0.9)	0	0	0	0
Dose not changed/NA/unknown	29 (12.7)	33 (14.4)	13 (18.8)	3 (3.8)	4 (4.2)	1 (3.2)
AE outcome			90		e e	
Recovered/resolved	13 (5.7)	15 (6.6)	7 (10.1)	2 (2.6)	2 (2.1)	1 (3.2)
Recovering/resolving	0	1 (0.4)	0	0	0	0
Not recovered/not resolved	19 (8.3)	20 (8.7)	8 (11.6)	1 (1.3)	3 (3.2)	0
Recovering/resolving		1 (0.4)		0		
Fatal		-	-	~ //		0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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A-617-01 Health Canada Table 8.12.8a Incidence of randomized tre	atment-emergent adver	se drug reaction Lu-PSMA-617 +BSC/BSoC		GFR level (FAS	Safety Set)	
Chichts ante Cahada	Normal					
The Canada da	Normal	+BSC/BS0C		В	SC/BSoC onl	V
7), 3) (C)	(N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) n (%)
ADR Weight decreased	, PO2					
Number of patients with at least one event	23 (10.0)	21 (9.2)	12 (17.4)	9 (11.5)	3 (3.2)	6 (19.4)
Maximum grade	Ch thin					
Grade 3 AEs	2 (0.9)	0	0	0	0	0
Grade 4 AEs	0 0	· 0	0 0	0 0	0	0 0
Grade 5 AEs	(O ₂	· / · · ·	U	U	0	U
Treatment-related AEs	9 (3.9)	8 (3.5)	6 (8.7)	1 (1.3)	0	1 (3.2)
SAEs	23 (10.0) 2 (0.9) 0 9 (3.9) 0 1 (0.4) 0	0	0	0	0	0
Action taken with PSMA-617	Viz. Cr	J	2.			
Drug withdrawn	1 (0.4)	1 (0.4)	² 000	0	0	0
Dose reduced	V 0 V	0	.0	0	0	0
	0	0	06.	0	0	0
Dose not changed/NA/unknown	22 (9.6)	20 (8.7)	12 (17.4)	9 (11.5)	3 (3.2)	6 (19.4)
Action taken with BSC/BSoC		OU.		6		
Drug withdrawn	0	0	0	720	0	0
Dose reduced	0	0 '%	0	0	0	0
Drug interrupted	0	0	0	0	0	0 (40 4)
Dose not changed/NA/unknown	23 (10.0)	21 (9.2)	12 (17.4)	9 (11.5)	3 (3.2)	6 (19.4)
AE outcome			900	· · · · · · · · · · · · · · · · · · ·	j.	
Recovered/resolved	5 (2.2)	2 (0.9)	5 (7.2)	2 (2.6)	O×0	2 (6.5)
Recovering/resolving	3 (1.3)	0	0	0	1 (1.1)	0
Not recovered/not resolved Recovered/resolved with sequelae	15 (6.6)	19 (8.3)	7 (10.1)	7 (9.0)	2 (2.1)	5 (16.1)

Final Version

	Lu-PSMA-617				
	+BSC/BSoC			BSC/BSoC onl	У
Normal	Mild	Moderate	Normal	Mild	Moderate
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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A-617-01 Health Canada				Final Version		
Table 8.12.8a Incidence of randomized trea	atment-emergent adver	se drug reactio	ons by baseline e	GFR level (FAS	S Safety Set)	
The Control of		Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only	.,
Chisanie Canada da de	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Modera (N=31 n (%)
ADR Oedema peripheral	. DO.		(1-1)	(/		
Number of patients with at least one event	20 (8.7)	25 (10.9)	7 (10.1)	4 (5.1)	6 (6.3)	4 (12.9
Maximum grade	Ch thin					
Grade 3 AEs	300	2 (0.9)	0	0	0	1 (3.2
Grade 4 AEs Grade 5 AEs	0 0	0 0	0 0	0 0	0 0	0 0
Treatment-related AEs	5 (2.2)	9 (3.9)	2 (2.9)	0	1 (1.1)	0
SAEs	CONTRINIO 0	1 (0.4)	0	0	0	0
Action taken with PSMA-617			25			
Drug withdrawn Dose reduced	07002/	1 (0.4)	0	0 0	0	0
Drug interrupted	0 6	0 1 (0.4)	0/2 .	0	0 0	0 0
Dose not changed/NA/unknown	20 (8.7)	23 (10.0)	7 (10.1)	4 (5.1)	6 (6.3)	4 (12.9
Action taken with BSC/BSoC		ON OFFICE		6		
Drug withdrawn	0	1 (0.4)	0	Z ₀ 0	0	0
Dose reduced Drug interrupted	0 0	0	0	1 (1.3) 1 (1.3)	0 0	0 0
Dose not changed/NA/unknown	20 (8.7)	24 (10.5)	7 (10.1)	3 (3.8)	6 (6.3)	4 (12.9
AE outcome			900		35	
Recovered/resolved	9 (3.9)	9 (3.9)	3 (4.3)	1 (1.3)	3 (3.2)	2 (6.5
Recovering/resolving Not recovered/not resolved	0	2 (0.9)	0	0	3 (3.3)	0 2 (0 7
Recovered/resolved with sequelae	11 (4.8) 0	14 (6.1) 0	4 (5.8) 0	3 (3.8)	3 (3.2)	3 (9.7 0
		-	_	10	ŭ	
Fatal	0	0	0	00	0	0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR Computition and control of the contr

nced Accelerator Applications, a Novartis Company			ı	Final Version		
A-617-01 Health Canada Table 8.12.8a Incidence of randomized treatments	atment-emergent adver	se drug reactic			Safety Set)	
On the Committee of the	<u> </u>	Lu-PSMA-617				
Ch dh Ca tha		+BSC/BSoC			SC/BSoC only	
(1) (1) (1) (1) (1) (1)	Normal	Mild	Moderate	Normal	Mild	Moderat
C/. O 40/2 47	(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31) n (%)
	n (%)	n (%)	n (%)	n (%)	n (%)	11 (70)
ADR Urinary tract infection	1000					
Number of patients with at least one event	19 (8.3)	30 (13.1)	12 (17.4)	1 (1.3)	1 (1.1)	0
Maximum grade	Ch Vh					
Grade 3 AEs	5 (2.2)	11 (4.8)	4 (5.8)	0	1 (1.1)	0
Grade 4 AEs	0 °C	. 0	0	0	0	0
Grade 5 AEs	0 '	2/ 0	0	0	0	0
Treatment-related AEs	1 (0.4)	3 (1.3)	0	0	0	0
Number of patients with at least one event Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Treatment-related AEs SAEs Action taken with PSMA-617 Drug withdrawn	4 (1.7)	6 (2.6)	3 (4.3)	0	1 (1.1)	0
Action taken with PSMA-617	Viz. Cr	3	2.			
Drug withdrawn	0, 0/2,	0	1 (1.4)	0	0	0
Dose reduced	0 0	0	0.	0	0	0
Drug interrupted	0	2 (0.9)	0/3.	Ö	Ö	0
Dose not changed/NA/unknown	19 (8.3)	29 (12.7)	12 (17.4)	1 (1.3)	1 (1.1)	0
Action taken with BSC/BSoC		000	6	Ž.		
Drug withdrawn	0	0	0	×>0	0	0
Dose reduced	0	0 %	0	10	Ö	Ö
Drug interrupted	0	2 (0.9)	1 (1.4)	0	0	0
Dose not changed/NA/unknown	19 (8.3)	29 (12.7)	12 (17.4)	1 (1.3)	1 (1.1)	0
AE outcome			0/0		Sr _	
Recovered/resolved	18 (7.9)	23 (10.0)	11 (15.9)	1 (1.3)	9 (1,1)	0
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	3 (1.3)	9 (3.9)	3 (4.3)	· 0	00	0
Recovered/resolved with sequelae	0	0	0	· (2): 0	0	0
Fatal .	0	0	0	00	0	0
Unknown	0	0	0	7 2 -	0	0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR Computition at least 10 patients are presented, Output ID: T-8-12-8a 2022-07-12 17:30 G-VAPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONIHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adreagers, as a Data Cutoff Date: 27JAN2021

-617-01 Health Canada Table 8.12.8a Incidence of randomized t			'	Final Version		
	reatment-emergent adve	rse drug reaction	ns by baseline e	GFR level (FAS	Safety Set)	
Chi de Sa Cap		Lu-PSMA-617 +BSC/BSoC		В	SC/BSoC only	v
TIES THE CONTROL OF T	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) n (%)
ADR Abdominal pain	C. Pop					
Number of patients with at least one event	18 (7.9)	30 (13.1)	11 (15.9)	6 (7.7)	3 (3.2)	4 (12.9)
Maximum grade	Cry Min					
Grade 3 AEs	2 (0.9)	3 (1.3)	1 (1.4)	0	0	1 (3.2)
Grade 4 AEs	0 0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	6 (2.6)	9 (3.9)	5 (7.2)	2 (2.6)	0	1 (3.2)
Number of patients with at least one event Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Treatment-related AEs SAEs	1 (0.4)	3 (1.3)	0	0	0	1 (3.2)
Action taken with PSMA-617	(1/2. C)	-3	2,			
Drug withdrawn	0, 0/2,	0	·?0/0	0	0	0
Dose reduced	VO V	0	0	0	0	0
Drug interrupted	0	0	06.	0	0	0
Dose not changed/NA/unknown	18 (7.9)	30 (13.1)	11 (15.9)	6 (7.7)	3 (3.2)	4 (12.9)
Action taken with BSC/BSoC		040		6		
Drug withdrawn	0	0	0	720	0	0
Dose reduced	0	0 8	0	0	0	0
Drug interrupted	0	1 (0.4)	0	0	0	0
Dose not changed/NA/unknown	18 (7.9)	29 (12.7)	11 (15.9)	6 (7.7)	3 (3.2)	4 (12.9)
AE outcome			900		's	
Recovered/resolved	14 (6.1)	22 (9.6)	7 (10.1)	3 (3.8)	9 (1,1)	2 (6.5)
Recovering/resolving	1 (0.4)	0	1 (1.4)	0	1 (1.1)	0
Not recovered/not resolved	5 (2.2)	8 (3.5)	3 (4.3)	2 (2.6)	1 (1.1)	2 (6.5)

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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				Final Version		
Table 8.12.8a Incidence of randomize	ed treatment-emergent adver	rse drug reaction		GFR level (FA	S Safety Set)	
The So the state		+BSC/BSoC			BSC/BSoC onl	İV
TIS THE COUNTY	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Modera (N=31) n (%)
ADR Dysgeusia	2/c. 10,	. ,				
Number of patients with at least one event	18 (7.9) 0 0 17 (7.4) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	15 (6.6)	4 (5.8)	0	2 (2.1)	1 (3.2)
Maximum grade	a Charles					
Grade 3 ÅEs		0	0	0	0	0
Grade 4 AEs	0 'C	0	0	0	0	0
Grade 5 AEs	0	2/ 0	0	0	0	0
Treatment-related AEs	17 (7.4)	11 (4.8)	4 (5.8)	0	1 (1.1)	1 (3.2)
SAEs	On The O	0 %	0	0	0	0
Action taken with PSMA-617	Ti, Cro.	O	2/2			
Drug withdrawn	0,0,2/	0	0	0	0	0
Dose reduced	3,0	0	0	0	0	0
Drug interrupted Dose not changed/NA/unknown	0 18 (7.9)	0 15 (6.6)	4 (5.8)	0 0	0 2 (2.1)	0 1 (3.2)
-	- ()	SO		X	` '	(- –)
Action taken with BSC/BSoC Drug withdrawn	9		0	0	0	0
Dose reduced	0 0	0	0	8 0	0 0	0 0
Drug interrupted	0	0	C ₂ 0	0	0	0
Dose not changed/NA/unknown	18 (7.9)	15 (6.6)	4 (5.8)	0 0	2 (2.1)	1 (3.2)
A.E			9/2		35	
AE outcome	C (2 C)	C (O C)			0.0	0
Recovered/resolved Recovering/resolving	6 (2.6) 0	6 (2.6) 0	0 0	0 0	0	0 0
Not recovered/not resolved	14 (6.1)	10 (4.4)	4 (5.8)	0	2 (2.1)	1 (3.2)
Recovered/resolved with sequelae	0.1)	0	4 (5.8)	4/2· 0	2 (2.1)	0
Fatal	0	0	0	700	0	0
Unknown	0	Ö	Ö	30	Ö	Ő
				0%		Pan

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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A-617-01 Health Canada Table 8.12.8a Incidence of randomized tre			'	Final Version		
	eatment-emergent adver	se drug reaction	ons by baseline e	GFR level (FAS	Safety Set)	
Cho of Can		Lu-PSMA-617 +BSC/BSoC		В:	SC/BSoC only	v
Ols Chie Co anada	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) n (%)
ADR Pyrexia	100 h					
Number of patients with at least one event	17 (7.4)	14 (6.1)	5 (7.2)	2 (2.6)	2 (2.1)	2 (6.5)
Maximum grade	Charles Charles	•	4 (4 4)		•	
Grade 3 AEs Grade 4 AEs	1 (0.4)	0	1 (1.4) 0	0 0	0 0	0 0
Grade 5 AEs	0	2/ 0	0	0	0	0
Number of patients with at least one event Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Treatment-related AEs SAEs Action taken with PSMA-617	2 (0.9)	1 (0.4)	1 (1.4)	0	0	1 (3.2)
SAEs	4 (1.7)	2 (0.9)	1 (1.4)	0	0	0
Action taken with PSMA-617	Tr. Cr.	0	92			
Drug withdrawn	0,002	0	0	0	0	0
Dose reduced	30 C	0	0	0	0	0
Drug interrupted Dose not changed/NA/unknown	0 17 (7.4)	1 (0.4) 13 (5.7)	1 (1.4) 4 (5.8)	0 2 (2.6)	0 2 (2.1)	0 2 (6.5)
Action taken with BSC/BSoC		OLIG	_	6		
Drug withdrawn Dose reduced	0	0	. 0	4 0	0 0	0
Drug interrupted	0	1 (0.4)	C 0	0	0	0 0
Dose not changed/NA/unknown	17 (7.4)	13 (5.7)	5 (7.2)	2 (2.6)	2 (2.1)	2 (6.5)
AE outcome					'S	
Recovered/resolved	17 (7.4)	14 (6.1)	5 (7.2)	2 (2.6)	2 (2.1)	1 (3.2)
Recovering/resolving Not recovered/not resolved	0	0 0	0	0	0	0 1 (3.2)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	O 0	0	0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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A-617-01 Health Canada Table 8.12.8a Incidence of randomized tr				Final Version		
	eatment-emergent adve	rse drug reaction	ons by baseline e	GFR level (FAS	Safety Set)	
The S. St. Can		Lu-PSMA-617 +BSC/BSoC		В:	SC/BSoC only	v
The Chief and day	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) n (%)
ADR Dizziness	3, 70,		. ,			
Number of patients with at least one event	16 (7.0)	21 (9.2)	7 (10.1)	2 (2.6)	3 (3.2)	4 (12.9)
Maximum grade	Cth thin	- ()			_	_
Grade 3 AEs	2 (0.9)	2 (0.9)	1 (1.4)	0	0	0
Grade 4 AEs Grade 5 AEs	0 0	? 0 2/ 0	0 0	0 0	0 0	0 0
Number of patients with at least one event Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Treatment-related AEs SAEs	5 (2.2)	6 (2.6)	2 (2.9)	2 (2.6)	0	0
SAEs	2 (0.9)	0	0	0	0	0
Action taken with PSMA-617	Viz. Cr.	٥	2.			
Drug withdrawn	0,000	0	0/0	0	0	0
Dose reduced	10 0 10	0	0	0	0	0
Drug interrupted Dose not changed/NA/unknown	0 16 (7.0)	0 21 (9.2)	7 (10.1)	0 2 (2.6)	0 3 (3.2)	0 4 (12.9)
Action taken with BSC/BSoC		Ollo		6		
Drug withdrawn	0	0	. 0	Z ₀	0	0
Dose reduced Drug interrupted	0	0 1 (0.4)	0 0	0	0 0	0 1 (3.2)
Dose not changed/NA/unknown	16 (7.0)	20 (8.7)	7 (10.1)	2 (2.6)	3 (3.2)	3 (9.7)
AE outcome			900	1	'S	
Recovered/resolved	12 (5.2)	11 (4.8)	3 (4.3)	0	9 (1,1)	3 (9.7)
Recovering/resolving	2 (0.9)	0	0	0	0	0
Not recovered/not resolved	3 (1.3)	11 (4.8)	4 (5.8)	2 (2.6)	2 (2.1)	1 (3.2)
Recovered/resolved with sequelae Fatal	0	0	1 (1.4)	0	0	0
Unknown	0 0	0 0	0 0	0	0	0 0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR Computity 15-812-88 2022-07-12 17:30

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7. Ox						
nced Accelerator Applications, a Novartis Company A-617-01 Health Canada				Final Version		
Table 8.12.8a Incidence of randomiz	zed treatment-emergent adver	Lu-PSMA-617				
CD 32 CD 47		+BSC/BSoC			SC/BSoC only	
Vis. Vij. Co. Wada	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Modera: (N=31) n (%)
ADR Headache	Carcy top					
Number of patients with at least one event	3 (1.3) 2 (0.9) 0 3 (1.3) 2 (0.9)	17 (7.4)	7 (10.1)	1 (1.3)	3 (3.2)	0
Maximum grade	a Ch Ch					
Grade 3 ĂEs	2 (0.9)	2 (0.9)	0	0	0	0
Grade 4 AEs	0 (C)	. 0	0	0	0	0
Grade 5 AEs	0	2/0	0	0	0	0
Treatment-related AEs	3 (1.3)	7 (3.1)	1 (1.4)	1 (1.3)	0	0
SAEs	2 (0.9)	0	0	0	0	0
Action taken with PSMA-617	17. 6	J	92			
Drug withdrawn	0, 0/2,	0	1 (1.4)	0	0	0
Dose reduced	3 -	0	0	0	0	0
Drug interrupted	1 (0.4)	0	0/6	0	0	0
Dose not changed/NA/unknown	13 (5.7)	17 (7.4)	6 (8.7)	1 (1.3)	3 (3.2)	0
Action taken with BSC/BSoC		C. C.	~~	6		
Drug withdrawn	1 (0.4)	0	0	ZZ0	0	0
Dose reduced	0	0 8	0	(0)	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	12 (5.2)	17 (7.4)	7 (10.1)	1 (1.3)	3 (3.2)	0
AE outcome			100	4	<i>'</i> C	
Recovered/resolved	7 (3.1)	11 (4.8)	3 (4.3)	0	9 (1,1)	0
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	6 (2.6)	6 (2.6)	4 (5.8)	1 (1.3)	2 (2.1)	0
Recovered/resolved with sequelae	1 (0.4)	0	0	0	0	0
Fatal Unknown	0	0 0	0	0	0	0
LINKU(MA)	/ 1		0	A	0	0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR eOFR Categories are ventices and section.
30 m/min).
Subgroups with at least 10 patients are presented.
Output ID: T-8-12-8a 2022-07-12 17:30
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A-617-01 Health Canada				Final Version		
Table 8.12.8a Incidence of randomized treate	ment-emergent adver			GFR level (FAS	S Safety Set)	
The Second Reserved		Lu-PSMA-617 +BSC/BSoC		r	BSC/BSoC only	V
The ante anada to	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Modera (N=31 n (%)
ADR Acute kidney injury	20°					
Number of patients with at least one event	7 (3.1)	24 (10.5)	13 (18.8)	0	3 (3.2)	8 (25.8
Maximum grade	Ch nh					
Grade 3 AEs	2 (0.9)	10 (4.4)	4 (5.8)	0	2 (2.1)	3 (9.7
Grade 4 AEs Grade 5 AEs	0	· 0	0 0	0 0	0 0	0 0
Number of patients with at least one event Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Treatment-related AEs SAEs Action taken with PSMA-617 Drug withdrawn Descriptions	3 (1.3)	8 (3.5)	7 (10.1)	0	0	0
SAEs	1 (0.4)	5 (2.2)	2 (2.9)	0	2 (2.1)	4 (12.9
Action taken with PSMA-617	The Co.		25			
Drug withdrawn	000	1 (0.4)	0	0	0	0
Dose reduced Drug interrupted	0	1 (0.4) 2 (0.9)	1 (1.4) 0	0 0	0 0	0 0
Dose not changed/NA/unknown	7 (3.1)	21 (9.2)	12 (17.4)	0	3 (3.2)	8 (25.8
Action taken with BSC/BSoC		OFF	7	Č		
Drug withdrawn	0	0	0	4 0	0	1 (3.2
Dose reduced Drug interrupted	0 0	1 (0.4) 1 (0.4)	0	0	0 0	0 2 (6.5
Dose not changed/NA/unknown	7 (3.1)	22 (9.6)	13 (18.8)	0 0	3 (3 2)	6 (19.4
AE outcome			200		3 (3.2)	
Recovered/resolved	6 (2.6)	15 (6.6)	7 (10.1)	0	3 (3.2)	5 (16.
Recovering/resolving Not recovered/not resolved	0 1 (0.4)	0 10 (4.4)	1 (1.4) 7 (10.1)	0	0.0	1 (3.2 2 (6.5
Recovered/resolved with sequelae	0	0	0	42.0	0	2 (0.5
	Ö	Ö		YOC	Ô	0
Fatal Unknown	U	0	0		0	U

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	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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nced Accelerator Applications, a Novartis Company A-617-01 Health Canada				Final Version	2.0-4-4 : 0-4)	
Table 8.12.8a Incidence of randomized tr		Lu-PSMA-617				
(C) (C) (D)		+BSC/BSoC		E	BSC/BSoC only	y
The the analy	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderat (N=31) n (%)
ADR Pancytopenia	2, to		. ,	\		
Number of patients with at least one event Maximum grade Grade 3 AEs Grade 4 AEs Grade 5 AEs Treatment-related AEs SAEs Action taken with PSMA-617	5 (2.2)	3 (1.3)	0	0	0	0
Maximum grade	Ch this					
Grade 3 AEs	2 (0.9)	0	0	0	0	0
Grade 4 AEs	1 (0.4)	1 (0.4)	0	0	0	0
Grade 5 AEs	1 (0.4)	1 (0.4)	0	0	0	0
Treatment-related AEs	3 (1.3)	3 (1.3)	0	0	0	0
SAEs	3 (1.3)	2 (0.9)	0	0	0	0
Action taken with PSMA-617	Viz. Crc.	0	2h			
Drug withdrawn	1 (0.4)	1 (0.4)	0	0	0	0
Dose reduced	3,0 ,6	0	0	0	0	0
Drug interrupted	0	0	0 €6≥.	0	0	0
Dose not changed/NA/unknown	4 (1.7)	2 (0.9)	0 200	0	0	0
Action taken with BSC/BSoC		170	-	6.	-	_
Drug withdrawn	1 (0.4)	1 (0.4)	. 0	550	0	0
Dose reduced	0	0 9	0	6	0	0
Drug interrupted Dose not changed/NA/unknown	1 (0.4) 3 (1.3)	0 2 (0.9)	0	0	0 0	0 0
AE outcome			965	* Q	35	
Recovered/resolved	1 (0.4)	0		0	Oxe	0
Recovering/resolving	0.4)	0	0	0	0	0
Not recovered/not resolved	2 (0.9)	1 (0.4)	0 0	0	86	0
Recovered/resolved with sequelae	1 (0.4)	0.4)	0	77.0	000	0
Fatal	1 (0.4)	1 (0.4)	0	700	0	0
	1 (0.1)					

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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A-617-01 Health Canada Table 8.12.8a Incidence of randomized tro				Final Version		
	eatment-emergent adve	rse drug reaction	ons by baseline e	GFR level (FAS	Safety Set)	
Cho To Cho Cho	*	Lu-PSMA-617 +BSC/BSoC		В	SC/BSoC only	v
Olis Co anada	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) n (%)
ADR Dry eye	2. Pos			, ,		
Number of patients with at least one event	4 (1.7)	9 (3.9)	3 (4.3)	1 (1.3)	0	1 (3.2)
Maximum grade	Ch Mh					
Grade 3 AEs	00	0	0	0	0	0
Grade 4 AEs	0 °C	0	0	0	0	0
Grade 5 AEs	402 0	2/0	0	0	0	0
Treatment-related AEs	4 (1.7)	8 (3.5)	1 (1.4)	0	0	1 (3.2)
SAEs	4 (1.7) 0 0 0 4 (1.7)	000	0	0	0	0
Action taken with PSMA-617	Viz. Cr	-0	2.			
Drug withdrawn	0, 0/2,	0	·200	0	0	0
2000 1000000		0	0	0	0	0
Drug interrupted	0	0 9 (3.9)	3 (4.3)	0 1 (1.3)	0	0
Dose not changed/NA/unknown	4 (1.7)	9 (3.9)	3 (4.3)	(1.3)	0	1 (3.2)
Action taken with BSC/BSoC		40	<i>C</i>	6		
Drug withdrawn	0	0	0	ZZ0	0	0
Dose reduced	0	0 %	1 (1.4)	0	0	0
Drug interrupted Dose not changed/NA/unknown	0 4 (1.7)	9 (3.9)	0 2 (2.9)	1 (1.3)	0 0	0 1 (3.2)
2000 Not onangod/W validiowii	1 (1.7)	0 (0.0)	2 (2.0)	1 (1.0)	,	1 (0.2)
AE outcome			Co	Y.	S	
Recovered/resolved	4 (1.7)	2 (0.9)	2 (2.9)	0	0,0	0
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	2 (0.9)	6 (2.6)	1 (1.4)	1 (1.3)	0.0	1 (3.2)
Recovered/resolved with sequelae	0	0	0	40.0	0	0
Fatal Unknown	0 0	0 1 (0.4)	0 0	0	0 0	0 0
	-	\/	~		-	-

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

eGFR categories are defined as follows: normal (eGFR >= 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 ml/min) and severe (eGFR GUPPDATAISAS, BIOMETRY/PRODIPROJECTS/PSMA617/VISIONHA_REQUESTS/HEALTHCANADA_REQUEST_03/PRODUCTION/TLF/PGM/t-ae-adregers.

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anced Accelerator Applications a Novertis Company						
A-617-01 Health Canada				Final Version		
Table 8.12.8a Incidence of randomized t		se drug reaction		GFR level (FAS	Safety Set)	
Va S. V. O. da		+BSC/BSoC		F	SC/BSoC only	N/
This anie Canada	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Modera (N=31) n (%)
ADR Vertigo	(c, 10)					
Number of patients with at least one event	C (4 (1.7) (1.7)	5 (2.2)	2 (2.9)	0	0	0
Maximum grade	Ch Th					
Grade 3 ĀEs	00	0	0	0	0	0
Grade 4 AEs	S 0 'C	. 0	0	0	0	0
Grade 5 AEs	0	2/ 0	0	0	0	0
Treatment-related AEs	C C 0	1 (0.4)	0	0	0	0
SAEs	1 (0.4)	0	0	0	0	0
Action taken with PSMA-617	Viz. Co.	0	22			
Drug withdrawn	0,000	0	0/0	0	0	0
Dose reduced	700 TO	0	0	0	0	0
Drug interrupted	0	0	6%.	0	0	0
Dose not changed/NA/unknown	4 (1.7)	5 (2.2)	2 (2.9)	0	0	0
Action taken with BSC/BSoC		070		6		
Drug withdrawn	1 (0.4)	0	. 0	720	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	3 (1.3)	5 (2.2)	2 (2.9)	0 0	0	0
AE outcome			Q ₀		35	
Recovered/resolved	2 (0.9)	3 (1.3)	1 (1.4)	0	0,0	0
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	2 (0.9)	2 (0.9)	1 (1.4)	0	00	0
Recovered/resolved with sequelae	0	0	0	47.0	0	0
Fatal Unknown	0	0 0	0 0	0	0	0
	11	11			0	0

Final Version

	Lu-PSMA-617					
	+BSC/BSoC		BSC/BSoC only			
Normal	Mild	Moderate	Normal	Mild	Moderate	
(N=229)	(N=229)	(N=69)	(N=78)	(N=95)	(N=31)	
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	

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.

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