Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Fatigue						
Number of patients with at least one event	100 (43.7)	96 (41.9)	32 (46.4)	19 (24.4)	18 (18.9)	10 (32.3)
Maximum grade						
Grade 3 AEs	15 (6.6)	12 (5.2)	4 (5.8)	0	0	3 (9.7)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	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						
Drug withdrawn	2 (0.9)	0	0	0	0	0
Dose reduced	1 (0.4)	1 (0.4)	0	0	0	0
Drug interrupted	0	0	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						
Drug withdrawn	3 (1.3)	2 (0.9)	0	0	0	0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						
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 sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	1 (0.4)	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 mouth						
Number of patients with at least one event	83 (36.2)	95 (41.5)	30 (43.5)	0	0	1 (3.2)
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	79 (34.5)	86 (37.6)	28 (40.6)	0	0	0
SAEs	0	0	0	0	0	0
Action taken with PSMA-617						
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						
Drug withdrawn	1 (0.4)	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	82 (35.8)	95 (41.5)	30 (43.5)	0	0	1 (3.2)
AE outcome						
Recovered/resolved	30 (13.1)	35 (15.3)	5 (7.2)	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	0	1 (3.2)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	2 (0.9)	2 (0.9)	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Nausea						
Number of patients with at least one event	76 (33.2)	82 (35.8)	28 (40.6)	12 (15.4)	14 (14.7)	8 (25.8)
Maximum grade						
Grade 3 AEs	4 (1.7)	2 (0.9)	1 (1.4)	1 (1.3)	0	0
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	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	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	76 (33.2)	82 (35.8)	28 (40.6)	12 (15.4)	14 (14.7)	8 (25.8)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	1 (1.3)	0	0
Dose reduced	0	1 (0.4)	0	1 (1.3)	0	0
Drug interrupted	1 (0.4)	2 (0.9)	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						
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	32 (14.0)	31 (13.5)	8 (11.6)	7 (9.0)	6 (6.3)	5 (16.1)
Recovered/resolved with sequelae	1 (0.4)	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	1 (0.4)	1 (0.4)	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
Subgroups with at least 10 patients are presented
Output ID: T-8-12-8a 2022-07-12 17:30
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Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Anaemia						
Number of patients with at least one event	68 (29.7)	77 (33.6)	22 (31.9)	12 (15.4)	8 (8.4)	7 (22.6)
Maximum grade						
Grade 3 AEs	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						
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 (19.4)
Action taken with BSC/BSoC						
Drug withdrawn	2 (0.9)	2 (0.9)	1 (1.4)	0	0	0
Dose reduced	0	0	0	0	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 (22.6)
AE outcome						
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)	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	0	1 (0.4)	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
Subgroups with at least 10 patients are presented
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Data Cutoff Date: 27JAN2021

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Decreased appetite						
Number of patients with at least one event	46 (20.1)	42 (18.3)	23 (33.3)	17 (21.8)	9 (9.5)	4 (12.9)
Maximum grade						
Grade 3 AEs	5 (2.2)	4 (1.7)	0	1 (1.3)	0	0
Grade 4 AEs	0	1 (0.4)	0	0	0	0
Grade 5 AEs	0	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	0	0	1 (1.4)	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	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						
Drug withdrawn	1 (0.4)	0	1 (1.4)	0	0	0
Dose reduced	0	0	0	1 (1.3)	0	0
Drug interrupted	0	0	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						
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	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
Subgroups with at least 10 patients are presented
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Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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						
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						
Grade 3 AEs	1 (0.4)	2 (0.9)	2 (2.9)	0	0	1 (3.2)
Grade 4 AEs	0	1 (0.4)	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	19 (8.3)	21 (9.2)	5 (7.2)	0	0	1 (3.2)
SAEs	1 (0.4)	2 (0.9)	2 (2.9)	0	0	1 (3.2)
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	1 (1.4)	0	0	0
Dose not changed/NA/unknown	41 (17.9)	50 (21.8)	15 (21.7)	7 (9.0)	10 (10.5)	6 (19.4)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	1 (0.4)	0	0	0	0
Dose not changed/NA/unknown	41 (17.9)	49 (21.4)	16 (23.2)	7 (9.0)	10 (10.5)	6 (19.4)
AE outcome						
Recovered/resolved	28 (12.2)	32 (14.0)	6 (8.7)	2 (2.6)	1 (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	17 (7.4)	22 (9.6)	10 (14.5)	5 (6.4)	9 (9.5)	3 (9.7)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	1 (0.4)	1 (0.4)	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
Subgroups with at least 10 patients are presented
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Data Cutoff Date: 27JAN2021

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Leukopenia						
Number of patients with at least one event	41 (17.9)	32 (14.0)	9 (13.0)	1 (1.3)	3 (3.2)	0
Maximum grade						
Grade 3 AEs	8 (3.5)	6 (2.6)	3 (4.3)	0	1 (1.1)	0
Grade 4 AEs	1 (0.4)	2 (0.9)	1 (1.4)	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	38 (16.6)	29 (12.7)	7 (10.1)	1 (1.3)	2 (2.1)	0
SAEs	0	2 (0.9)	0	0	0	0
Action taken with PSMA-617						
Drug withdrawn	1 (0.4)	8 (3.5)	0	0	0	0
Dose reduced	3 (1.3)	2 (0.9)	1 (1.4)	0	0	0
Drug interrupted	4 (1.7)	7 (3.1)	0	0	0	0
Dose not changed/NA/unknown	39 (17.0)	30 (13.1)	8 (11.6)	1 (1.3)	3 (3.2)	0
Action taken with BSC/BSoC						
Drug withdrawn	1 (0.4)	1 (0.4)	0	0	0	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)	0
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)	0
Recovered/resolved with sequelae	0	1 (0.4)	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
Subgroups with at least 10 patients are presented
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Data Cutoff Date: 27JAN2021

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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						
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						
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
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	21 (9.2)	25 (10.9)	11 (15.9)	0	0	0
SAEs	0	0	0	1 (1.3)	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	1 (0.4)	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						
Drug withdrawn	0	1 (0.4)	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	1 (0.4)	1 (0.4)	0	0	0	0
Dose not changed/NA/unknown	39 (17.0)	39 (17.0)	19 (27.5)	2 (2.6)	2 (2.1)	2 (6.5)
AE outcome						
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
Not recovered/not resolved	6 (2.6)	12 (5.2)	7 (10.1)	1 (1.3)	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

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Thrombocytopenia						
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						
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)	5 (2.2)	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	36 (15.7)	35 (15.3)	11 (15.9)	0	0	0
SAEs	1 (0.4)	2 (0.9)	0	0	0	0
Action taken with PSMA-617						
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	5 (2.2)	10 (4.4)	3 (4.3)	0	0	0
Dose not changed/NA/unknown	37 (16.2)	32 (14.0)	9 (13.0)	5 (6.4)	3 (3.2)	1 (3.2)
Action taken with BSC/BSoC						
Drug withdrawn	3 (1.3)	1 (0.4)	1 (1.4)	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	1 (0.4)	2 (0.9)	0	0	0	0
Dose not changed/NA/unknown	39 (17.0)	38 (16.6)	11 (15.9)	5 (6.4)	3 (3.2)	1 (3.2)
AE outcome						
Recovered/resolved	10 (4.4)	10 (4.4)	5 (7.2)	1 (1.3)	0	0
Recovering/resolving	1 (0.4)	0	0	0	0	0
Not recovered/not resolved	32 (14.0)	31 (13.5)	8 (11.6)	4 (5.1)	3 (3.2)	1 (3.2)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	1 (1.4)	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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						
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						
Grade 3 AEs	2 (0.9)	2 (0.9)	1 (1.4)	1 (1.3)	0	0
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	21 (9.2)	25 (10.9)	16 (23.2)	2 (2.6)	1 (1.1)	0
SAEs	3 (1.3)	1 (0.4)	1 (1.4)	1 (1.3)	0	0
Action taken with PSMA-617						
Drug withdrawn	1 (0.4)	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	37 (16.2)	45 (19.7)	17 (24.6)	5 (6.4)	5 (5.3)	3 (9.7)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	1 (0.4)	0	0	0	0
Drug interrupted	1 (0.4)	0	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)
AE outcome						
Recovered/resolved	29 (12.7)	35 (15.3)	15 (21.7)	4 (5.1)	5 (5.3)	2 (6.5)
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	12 (5.2)	13 (5.7)	3 (4.3)	1 (1.3)	0	1 (3.2)
Recovered/resolved with sequelae	1 (0.4)	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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						
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						
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	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	0	0	0	0	0	0
Action taken with PSMA-617						
Drug withdrawn	0	2 (0.9)	0	0	0	0
Dose reduced	0	1 (0.4)	1 (1.4)	0	0	0
Drug interrupted	0	1 (0.4)	0	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						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	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						
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
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Weight decreased						
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						
Grade 3 AEs	2 (0.9)	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	9 (3.9)	8 (3.5)	6 (8.7)	1 (1.3)	0	1 (3.2)
SAEs	0	0	0	0	0	0
Action taken with PSMA-617						
Drug withdrawn	1 (0.4)	1 (0.4)	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	22 (9.6)	20 (8.7)	12 (17.4)	9 (11.5)	3 (3.2)	6 (19.4)
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	23 (10.0)	21 (9.2)	12 (17.4)	9 (11.5)	3 (3.2)	6 (19.4)
AE outcome						
Recovered/resolved	5 (2.2)	2 (0.9)	5 (7.2)	2 (2.6)	0	2 (6.5)
Recovering/resolving	3 (1.3)	0	0	0	1 (1.1)	0
Not recovered/not resolved	15 (6.6)	19 (8.3)	7 (10.1)	7 (9.0)	2 (2.1)	5 (16.1)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Oedema peripheral						
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						
Grade 3 AEs	0	2 (0.9)	0	0	0	1 (3.2)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	5 (2.2)	9 (3.9)	2 (2.9)	0	1 (1.1)	0
SAEs	0	1 (0.4)	0	0	0	0
Action taken with PSMA-617						
Drug withdrawn	0	1 (0.4)	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	1 (0.4)	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						
Drug withdrawn	0	1 (0.4)	0	0	0	0
Dose reduced	0	0	0	1 (1.3)	0	0
Drug interrupted	0	0	0	1 (1.3)	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						
Recovered/resolved	9 (3.9)	9 (3.9)	3 (4.3)	1 (1.3)	3 (3.2)	2 (6.5)
Recovering/resolving	0	2 (0.9)	0	0	0	0
Not recovered/not resolved	11 (4.8)	14 (6.1)	4 (5.8)	3 (3.8)	3 (3.2)	3 (9.7)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Urinary tract infection						
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						
Grade 3 AEs	5 (2.2)	11 (4.8)	4 (5.8)	0	1 (1.1)	0
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	1 (0.4)	3 (1.3)	0	0	0	0
SAEs	4 (1.7)	6 (2.6)	3 (4.3)	0	1 (1.1)	0
Action taken with PSMA-617						
Drug withdrawn	0	0	1 (1.4)	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	2 (0.9)	0	0	0	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						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
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						
Recovered/resolved	18 (7.9)	23 (10.0)	11 (15.9)	1 (1.3)	1 (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	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

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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						
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						
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
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)
SAEs	1 (0.4)	3 (1.3)	0	0	0	1 (3.2)
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	18 (7.9)	30 (13.1)	11 (15.9)	6 (7.7)	3 (3.2)	4 (12.9)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	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						
Recovered/resolved	14 (6.1)	22 (9.6)	7 (10.1)	3 (3.8)	1 (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)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Dysgeusia						
Number of patients with at least one event	18 (7.9)	15 (6.6)	4 (5.8)	0	2 (2.1)	1 (3.2)
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	17 (7.4)	11 (4.8)	4 (5.8)	0	1 (1.1)	1 (3.2)
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	18 (7.9)	15 (6.6)	4 (5.8)	0	2 (2.1)	1 (3.2)
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	18 (7.9)	15 (6.6)	4 (5.8)	0	2 (2.1)	1 (3.2)
AE outcome						
Recovered/resolved	6 (2.6)	6 (2.6)	0	0	0	0
Recovering/resolving	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	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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						
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						
Grade 3 AEs	1 (0.4)	0	1 (1.4)	0	0	0
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	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						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	1 (0.4)	1 (1.4)	0	0	0
Dose not changed/NA/unknown	17 (7.4)	13 (5.7)	4 (5.8)	2 (2.6)	2 (2.1)	2 (6.5)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	1 (0.4)	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						
Recovered/resolved	17 (7.4)	14 (6.1)	5 (7.2)	2 (2.6)	2 (2.1)	1 (3.2)
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	0	0	0	0	0	1 (3.2)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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						
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						
Grade 3 AEs	2 (0.9)	2 (0.9)	1 (1.4)	0	0	0
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	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						
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	16 (7.0)	21 (9.2)	7 (10.1)	2 (2.6)	3 (3.2)	4 (12.9)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	0	1 (0.4)	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						
Recovered/resolved	12 (5.2)	11 (4.8)	3 (4.3)	0	1 (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	0	0	1 (1.4)	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Headache						
Number of patients with at least one event	13 (5.7)	17 (7.4)	7 (10.1)	1 (1.3)	3 (3.2)	0
Maximum grade						
Grade 3 AEs	2 (0.9)	2 (0.9)	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	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						
Drug withdrawn	0	0	1 (1.4)	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	1 (0.4)	0	0	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						
Drug withdrawn	1 (0.4)	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	12 (5.2)	17 (7.4)	7 (10.1)	1 (1.3)	3 (3.2)	0
AE outcome						
Recovered/resolved	7 (3.1)	11 (4.8)	3 (4.3)	0	1 (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	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Acute kidney injury						
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						
Grade 3 AEs	2 (0.9)	10 (4.4)	4 (5.8)	0	2 (2.1)	3 (9.7)
Grade 4 AEs	0	0	0	0	0	0
Grade 5 AEs	0	0	0	0	0	0
Treatment-related AEs	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						
Drug withdrawn	0	1 (0.4)	0	0	0	0
Dose reduced	0	1 (0.4)	1 (1.4)	0	0	0
Drug interrupted	0	2 (0.9)	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						
Drug withdrawn	0	0	0	0	0	1 (3.2)
Dose reduced	0	1 (0.4)	0	0	0	0
Drug interrupted	0	1 (0.4)	0	0	0	2 (6.5)
Dose not changed/NA/unknown	7 (3.1)	22 (9.6)	13 (18.8)	0	3 (3.2)	6 (19.4)
AE outcome						
Recovered/resolved	6 (2.6)	15 (6.6)	7 (10.1)	0	3 (3.2)	5 (16.1)
Recovering/resolving	0	0	1 (1.4)	0	0	1 (3.2)
Not recovered/not resolved	1 (0.4)	10 (4.4)	7 (10.1)	0	0	2 (6.5)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	0	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Pancytopenia						
Number of patients with at least one event	5 (2.2)	3 (1.3)	0	0	0	0
Maximum grade						
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						
Drug withdrawn	1 (0.4)	1 (0.4)	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	4 (1.7)	2 (0.9)	0	0	0	0
Action taken with BSC/BSoC						
Drug withdrawn	1 (0.4)	1 (0.4)	0	0	0	0
Dose reduced	0	0	0	0	0	0
Drug interrupted	1 (0.4)	0	0	0	0	0
Dose not changed/NA/unknown	3 (1.3)	2 (0.9)	0	0	0	0
AE outcome						
Recovered/resolved	1 (0.4)	0	0	0	0	0
Recovering/resolving	0	0	0	0	0	0
Not recovered/not resolved	2 (0.9)	1 (0.4)	0	0	0	0
Recovered/resolved with sequelae	1 (0.4)	0	0	0	0	0
Fatal	1 (0.4)	1 (0.4)	0	0	0	0
Unknown	0	1 (0.4)	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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						
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						
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	4 (1.7)	8 (3.5)	1 (1.4)	0	0	1 (3.2)
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	4 (1.7)	9 (3.9)	3 (4.3)	1 (1.3)	0	1 (3.2)
Action taken with BSC/BSoC						
Drug withdrawn	0	0	0	0	0	0
Dose reduced	0	0	1 (1.4)	0	0	0
Drug interrupted	0	0	0	0	0	0
Dose not changed/NA/unknown	4 (1.7)	9 (3.9)	2 (2.9)	1 (1.3)	0	1 (3.2)
AE outcome						
Recovered/resolved	4 (1.7)	2 (0.9)	2 (2.9)	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	1 (3.2)
Recovered/resolved with sequelae	0	0	0	0	0	0
Fatal	0	0	0	0	0	0
Unknown	0	1 (0.4)	0	0	0	0

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
Subgroups with at least 10 patients are presented
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Data Cutoff Date: 27JAN2021

Table 8.12.8a Incidence of randomized treatment-emergent adverse drug reactions by baseline eGFR level (FAS Safety Set)

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	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 Vertigo						
Number of patients with at least one event	4 (1.7)	5 (2.2)	2 (2.9)	0	0	0
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	0	1 (0.4)	0	0	0	0
SAEs	1 (0.4)	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	4 (1.7)	5 (2.2)	2 (2.9)	0	0	0
Action taken with BSC/BSoC						
Drug withdrawn	1 (0.4)	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	3 (1.3)	5 (2.2)	2 (2.9)	0	0	0
AE outcome						
Recovered/resolved	2 (0.9)	3 (1.3)	1 (1.4)	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	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

	Lu-PSMA-617 +BSC/BSoC			BSC/BSoC only		
	Normal (N=229) n (%)	Mild (N=229) n (%)	Moderate (N=69) n (%)	Normal (N=78) n (%)	Mild (N=95) n (%)	Moderate (N=31) 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 <30 ml/min).
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