

Table 8.12.6f Adverse Drug Reactions - Randomized Treatment-Emergent Adverse Events Regardless of Study Drug Relationship, by Primary System Organ Class, ADR Group and Age groups (FAS Safety Set)

Risk System Organ Class Adverse Drug Reaction	Lu-PSMA-617 +BSC/BSoC						BSC/BSoC only					
	<65 (N=142)		>=65-<75 (N=244)		>=75 (N=143)		<65 (N=42)		>=65-<75 (N=100)		>=75 (N=63)	
	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)
Blood and lymphatic system disorders												
ADR Anaemia	34 (23.9)	14 (9.9)	75 (30.7)	29 (11.9)	59 (41.3)	25 (17.5)	3 (7.1)	2 (4.8)	14 (14.0)	3 (3.0)	10 (15.9)	5 (7.9)
ADR Leukopenia	20 (14.1)	5 (3.5)	36 (14.8)	9 (3.7)	27 (18.9)	8 (5.6)	1 (2.4)	1 (2.4)	3 (3.0)	0	0	0
ADR Lymphopenia	21 (14.8)	8 (5.6)	36 (14.8)	19 (7.8)	18 (12.6)	14 (9.8)	1 (2.4)	0	5 (5.0)	1 (1.0)	2 (3.2)	0
ADR Pancytopenia	3 (2.1)	3 (2.1)	3 (1.2)	1 (0.4)	3 (2.1)	3 (2.1)	0	0	0	0	0	0
ADR Thrombocytopenia	21 (14.8)	12 (8.5)	40 (16.4)	16 (6.6)	30 (21.0)	14 (9.8)	2 (4.8)	1 (2.4)	2 (2.0)	1 (1.0)	5 (7.9)	0
Ear and labyrinth disorders												
ADR Vertigo	4 (2.8)	0	6 (2.5)	0	1 (0.7)	0	0	0	0	0	0	0
Eye disorders												
ADR Dry eye	4 (2.8)	0	8 (3.3)	0	4 (2.8)	0	0	0	2 (2.0)	0	0	0

Gastrointestinal disorders

Numbers (n) represent counts of subjects.

A subject with multiple severity grades for events contributing to an ADR is only counted under the maximum grade.

Coded using MedDRA version 24.0, CTCAE version 5.0, Case Retrieval Strategy version released 14JUN2021.

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	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)
Gastrointestinal disorders (Continued)												
ADR Abdominal pain	15 (10.6)	2 (1.4)	27 (11.1)	3 (1.2)	17 (11.9)	1 (0.7)	2 (4.8)	1 (2.4)	8 (8.0)	0	3 (4.8)	0
ADR Constipation	30 (21.1)	1 (0.7)	51 (20.9)	4 (1.6)	26 (18.2)	1 (0.7)	4 (9.5)	0	12 (12.0)	1 (1.0)	7 (11.1)	0
ADR Diarrhea	22 (15.5)	2 (1.4)	54 (22.1)	1 (0.4)	24 (16.8)	1 (0.7)	1 (2.4)	0	2 (2.0)	1 (1.0)	3 (4.8)	0
ADR Dry mouth	51 (35.9)	0	93 (38.1)	0	64 (44.8)	0	0	0	1 (1.0)	0	0	0
ADR Nausea	55 (38.7)	2 (1.4)	90 (36.9)	3 (1.2)	42 (29.4)	2 (1.4)	5 (11.9)	0	17 (17.0)	1 (1.0)	12 (19.0)	0
ADR Vomiting	27 (19.0)	1 (0.7)	53 (21.7)	2 (0.8)	21 (14.7)	2 (1.4)	4 (9.5)	0	6 (6.0)	1 (1.0)	3 (4.8)	0
General disorders and administration site conditions												
ADR Decreased appetite	21 (14.8)	1 (0.7)	53 (21.7)	6 (2.5)	38 (26.6)	3 (2.1)	5 (11.9)	0	13 (13.0)	0	12 (19.0)	1 (1.6)

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	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)
ADR Fatigue	58 (40.8)	7 (4.9)	102 (41.8)	14 (5.7)	68 (47.6)	10 (7.0)	7 (16.7)	0	24 (24.0)	2 (2.0)	16 (25.4)	1 (1.6)
ADR Oedema peripheral	13 (9.2)	0	24 (9.8)	1 (0.4)	15 (10.5)	1 (0.7)	0	0	9 (9.0)	0	5 (7.9)	1 (1.6)
ADR Pyrexia	13 (9.2)	0	15 (6.1)	1 (0.4)	8 (5.6)	1 (0.7)	1 (2.4)	0	3 (3.0)	0	3 (4.8)	0
ADR Weight decreased	8 (5.6)	0	25 (10.2)	1 (0.4)	24 (16.8)	1 (0.7)	1 (2.4)	0	11 (11.0)	0	6 (9.5)	0
Nervous system disorders												
ADR Dizziness	13 (9.2)	2 (1.4)	16 (6.6)	2 (0.8)	15 (10.5)	1 (0.7)	2 (4.8)	0	2 (2.0)	0	5 (7.9)	0
ADR Dysgeusia	8 (5.6)	0	16 (6.6)	0	13 (9.1)	0	0	0	2 (2.0)	0	1 (1.6)	0
ADR Headache	17 (12.0)	1 (0.7)	14 (5.7)	2 (0.8)	6 (4.2)	1 (0.7)	0	0	2 (2.0)	0	2 (3.2)	0
Renal and urinary disorders												
ADR Acute kidney injury	8 (5.6)	3 (2.1)	22 (9.0)	8 (3.3)	15 (10.5)	6 (4.2)	2 (4.8)	2 (4.8)	3 (3.0)	1 (1.0)	7 (11.1)	3 (4.8)

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	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)
ADR Urinary tract infection	14 (9.9)	1 (0.7)	29 (11.9)	12 (4.9)	18 (12.6)	7 (4.9)	0	0	0	0	2 (3.2)	1 (1.6)

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