Table 8.12.6g Adverse Drug Reactions - Randomized Treatment-Emergent Serious 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	5 (3.5)	4 (2.8)	7 (2.9)	7 (2.9)	3 (2.1)	3 (2.1)	0	0	0	0	1 (1.6)	0
ADR Leukopenia	0	0	1 (0.4)	1 (0.4)	1 (0.7)	1 (0.7)	0	0	0	0	0	0
ADR Pancytopenia	3 (2.1)	3 (2.1)	1 (0.4)	1 (0.4)	2 (1.4)	2 (1.4)	0	0	0	0	0	0
ADR Thrombocytopenia	1 (0.7)	1 (0.7)	1 (0.4)	1 (0.4)	1 (0.7)	1 (0.7)	0	0	0	0	0	0
Ear and labyrinth disorders												
ADR Vertigo	0	0	1 (0.4)	0	0	0	0	0	0	0	0	0
Gastrointestinal disorders												
ADR Abdominal pain	1 (0.7)	1 (0.7)	3 (1.2)	2 (0.8)	0	0	1 (2.4)	1 (2.4)	0	0	0	0
ADR Constipation	2 (1.4)	1 (0.7)	2 (0.8)	2 (0.8)	1 (0.7)	1 (0.7)	0	0	1 (1.0)	1 (1.0)	0	0
ADR Diarrhea	0	0	0	0	0	0	0	0	1 (1.0)	1 (1.0)	0	0
ADR Nausea	1 (0.7)	1 (0.7)	0	0	2 (1.4)	1 (0.7)	0	0	1 (1.0)	1 (1.0)	0	0
ADR Vomiting	1 (0.7)	1 (0.7)	2 (0.8)	1 (0.4)	2 (1.4)	1 (0.7)	0	0	1 (1.0)	1 (1.0)	0	0

General disorders and administration
site conditions

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.
Output ID: t-8-12-6g 2022-06-10 18:18
G:\APPDATA\SAS_BIOMETRY\PROD\PROJECTS\PSMA617\VISION\HA_REQUESTS\HEALTHCANADA_REQUEST_02\PRODUCTION\TLF\PGM\t-teae-soc-adr-age.sas
Data Cutoff Date: 27JAN2021

Final Version

Table 8.12.6g Adverse Drug Reactions - Randomized Treatment-Emergent Serious 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 (%)
General disorders and administration site conditions (Continued)												
ADR Decreased appetite	0	0	0	0	1 (0.7)	0	0	0	0	0	0	0
ADR Fatigue	0	0	2 (0.8)	1 (0.4)	0	0	0	0	0	0	0	0
ADR Oedema peripheral	0	0	1 (0.4)	1 (0.4)	0	0	0	0	0	0	0	0
ADR Pyrexia	3 (2.1)	0	2 (0.8)	0	2 (1.4)	1 (0.7)	0	0	0	0	0	0
Nervous system disorders												
ADR Dizziness	2 (1.4)	1 (0.7)	0	0	0	0	0	0	0	0	0	0
ADR Headache	1 (0.7)	1 (0.7)	1 (0.4)	0	0	0	0	0	0	0	0	0
Renal and urinary disorders												
ADR Acute kidney injury	2 (1.4)	2 (1.4)	4 (1.6)	4 (1.6)	3 (2.1)	2 (1.4)	2 (4.8)	2 (4.8)	2 (2.0)	1 (1.0)	3 (4.8)	3 (4.8)
ADR Urinary tract infection	1 (0.7)	1 (0.7)	8 (3.3)	8 (3.3)	4 (2.8)	4 (2.8)	0	0	0	0	1 (1.6)	1 (1.6)

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.
Output ID: t-8-12-6g 2022-06-10 18:18
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Data Cutoff Date: 27JAN2021