Advanced Accelerator Applications, a Novartis Company PSMA-617-01 Health Canada

Final Version

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)

	>		_0_												
Ye, 0	2.	.C.	47°	Lu-PSN	1A-617					BSC/I	3SoC				
4/6	47x	+BSC/BSoC							only						
-0,	. 6	<6	55	>=65	-<75	>=75		<65		>=65-<75		>=75			
	7 C	(N=142)		(N=2	(N=244)		(N=143)		(N=42)		(N=100)		63)		
	V1: V1	All	Grade	All	Grade	All	Grade	All	Grade	All	Grade	All	Grade		
Risk System Organ Class	97,	grades	>=3	grades	>=3	grades	>=3	grades	>=3	grades	>=3	grades	>=3		
Adverse Drug Reaction	, 4C0	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
		8	>	C	0.	•	•	•			•				
Blood and lymphatic system of	disorders	82		6.	Sp.										
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		
			6	Co		. 4	٠ کے								
Ear and labyrinth disorders				C			0								
ADR Vertigo		4 (2.8)	0	6 (2.5)	ر 0	1 (0.7)	0	0	0	0	0	0	0		
				· (2/;	C		S.								
Eye disorders				14	C.		8) ろ・							
ADR Dry eye		4 (2.8)	0	8 (3.3)	50 8	4 (2.8)	0	Q 0	0	2 (2.0)	0	0	0		
					7),	Co		5/2							
Gastrointestinal disorders						0.		×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-8-12-6f 2022-06-10 18:18

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Advanced Accelerator Applications, a Novartis Company PSMA-617-01 Health Canada

Final Version

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)

()	-0												
Lu-PSMA-617							BSC/BSoC						
+BSC/BSoC							only						
<6	<65 >=65-<75				>=75 <		<65 >=		-<75	>=7	75		
(N=	(N=142)		(N=244)		(N=143)		(N=42)		(N=100)		(N=63)		
All	Grade	All	Grade	All	Grade	All	Grade	All	Grade	All	Grade		
grades	>=3	grades	>=3	grades	>=3	grades	>=3	grades	>=3	grades	>=3		
n (%)	n (%)	n (%)	_ n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
C. Y	>	C,	0.										
97	0	6	3										
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		
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		
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		
51 (35.9)	0	93 (38.1)	0	64 (44.8)	0	0	0	1 (1.0)	0	0	0		
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		
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		
		Co		×	0								
		05 X	3		3								
		· Q/:	YC2		S.								
	1 (0.7)	53 (21.7)	6 (2.5)	38 (26.6)	3 (2.1) 9	5 (11.9)	0	13 (13.0)	0	12 (19.0)	1 (1.6)		
	(N='All grades n (%) 15 (10.6) 30 (21.1) 22 (15.5) 51 (35.9) 55 (38.7) 27 (19.0)	(N=142) All Grade grades >=3 n (%) n (%) 15 (10.6) 2 (1.4) 30 (21.1) 1 (0.7) 22 (15.5) 2 (1.4) 51 (35.9) 0 55 (38.7) 2 (1.4) 27 (19.0) 1 (0.7) 21 (14.8) 1 (0.7)	+BSC/ <65 >=65 (N=142) (N=2) All Grade grades >=3 grades n (%) n (%) n (%) 15 (10.6) 2 (1.4) 27 (11.1) 30 (21.1) 1 (0.7) 51 (20.9) 22 (15.5) 2 (1.4) 54 (22.1) 51 (35.9) 0 93 (38.1) 55 (38.7) 2 (1.4) 90 (36.9) 27 (19.0) 1 (0.7) 53 (21.7)	+BSC/BSoC <65 (N=142) All Grade grades >=3 n (%) 15 (10.6) 2 (1.4) 27 (11.1) 3 (1.2) 30 (21.1) 1 (0.7) 51 (20.9) 4 (1.6) 22 (15.5) 2 (1.4) 54 (22.1) 1 (0.4) 51 (35.9) 0 93 (38.1) 0 55 (38.7) 2 (1.4) 90 (36.9) 3 (1.2) 27 (19.0) 1 (0.7) 53 (21.7) 2 (0.8) 21 (14.8) 1 (0.7) 53 (21.7) 6 (2.5)	+BSC/BSoC <65	+BSC/BSoC <65	+BSC/BSoC	+BSC/BSoC <65	+BSC/BSoC on <65 (N=142) >=65-<75 (N=244) >=75 (N=143) <65 (N=42) >=65 (N=142) All Grade grades All Grade grades	+BSC/BSoC only <65 >=65-<75 >=75 <65 >=65-<75 >=65-<75 (N=142) (N=244) (N=143) (N=42) (N=100) All Grade All Grade All Grade Grade	+BSC/BSoC only <65 (N=142) >=65-<75 (N=244) >=75 (N=143) <65 (N=42) >=65-<75 (N=100) >=65-<75 (N=100) >=75 (N=100)		

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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Advanced Accelerator Applications, a Novartis Company PSMA-617-01 Health Canada

Final Version

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)

		()	- ^											
10 Vo.		· Ca	3h.	Lu-PSN	/IA-617					BSC/E	3SoC			
475 4	うx .	+BSC/BSoC						only						
-0,	.6	<6	5/ 2	>=65	>=65-<75 >=75		<6	<65		>=65-<75		75		
		(N=142)		(N=2	(N=244) (N=143)		(N=42)		(N=100)		(N=63)			
X X	1: 4	All	Grade	All	Grade	All	Grade	All	Grade	All	Grade	All	Grade	
Risk System Organ Class	9/2	grades	>=3	grades	>=3	grades	>=3	grades	>=3	grades	>=3	grades	>=3	
Adverse Drug Reaction	, C0	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
	. (2	>	C										
ADR Fatigue		58 (40.8)	7 (4.9)	102	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)	
-		201	J. X.	(41.8)	5									
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)	00	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)	7 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	
				5		` <i>\</i>								
Nervous system disorders			6	C		` 4)	5							
ADR Dizziness		13 (9.2)	2 (1.4)	16 (6.6)	2 (0.8)	15 (10.5)	9 (0.7)	2 (4.8)	0	2 (2.0)	0	5 (7.9)	0	
ADR Dysgeusia		8 (5.6)	0	16 (6.6)	5 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	
				16)	C		Ś	25						
Renal and urinary disorders				. (15	/		10						
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)	
Ni	- 4 1 - 1 4	_				U		9/						

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.

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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)

TICAL SAN	BSC/BSoC only											
	<65 >=65-<75 (N=142) (N=244)					75 143)	<65 (N=42)		>=65-<75 (N=100)		>=75 (N=63)	
~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	All	Grade	All	Grade	All	Grade	All	Grade	All	Grade	All	Grade
Risk System Organ Class	grades	>=3	grades	>=3	grades	>=3	grades	>=3	grades	>=3	grades	>=3
Adverse Drug Reaction	n (%)	n (%)	n (%)	_ n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	.0. 9	· *	C									
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)

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.

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