

Table 1
Treatment-Emergent Adverse Events Occurring in at Least 5% of the Subjects
Safety Analysis Set

MedDRA (V19.1) System Organ Class Preferred Term	Initial Dose Level Assigned			All dosing groups (N = 61)
	< 1 x 10 ¹² vp (N = 6)	1 - 3 x 10 ¹² vp (N = 26)	> 3 x 10 ¹² vp (N = 29)	
Any TEAE	6 (100%)	26 (100%)	29 (100%)	61 (100%)
General disorders and administration	5 (83.3%)	26 (100%)	29 (100%)	60 (98.4%)
Pyrexia	2 (33.3%)	20 (76.9%)	23 (79.3%)	45 (73.8%)
Chills		18 (69.2%)	23 (79.3%)	41 (67.2%)
Fatigue	2 (33.3%)	10 (38.5%)	14 (48.3%)	26 (42.6%)
Asthenia	3 (50.0%)	9 (34.6%)	7 (24.1%)	19 (31.1%)
Influenza like illness		7 (26.9%)	6 (20.7%)	13 (21.3%)
Oedema peripheral	3 (50.0%)	2 (7.7%)	5 (17.2%)	10 (16.4%)
Chest pain	1 (16.7%)	3 (11.5%)	2 (6.9%)	6 (9.8%)
Malaise		2 (7.7%)	3 (10.3%)	5 (8.2%)
Gastrointestinal disorders	4 (66.7%)	22 (84.6%)	24 (82.8%)	50 (82.0%)
Nausea	1 (16.7%)	11 (42.3%)	12 (41.4%)	24 (39.3%)
Vomiting	1 (16.7%)	10 (38.5%)	13 (44.8%)	24 (39.3%)
Diarrhoea	1 (16.7%)	7 (26.9%)	12 (41.4%)	20 (32.8%)
Abdominal pain		3 (11.5%)	10 (34.5%)	13 (21.3%)
Constipation	2 (33.3%)	6 (23.1%)	4 (13.8%)	12 (19.7%)
Dry mouth		1 (3.8%)	6 (20.7%)	7 (11.5%)
Abdominal pain upper		1 (3.8%)	4 (13.8%)	5 (8.2%)
Dyspepsia		2 (7.7%)	3 (10.3%)	5 (8.2%)
Musculoskeletal and connective tissue	4 (66.7%)	19 (73.1%)	17 (58.6%)	40 (65.6%)
Musculoskeletal pain	1 (16.7%)	6 (23.1%)	7 (24.1%)	14 (23.0%)
Back pain	1 (16.7%)	5 (19.2%)	7 (24.1%)	13 (21.3%)
Myalgia	1 (16.7%)	4 (15.4%)	3 (10.3%)	8 (13.1%)
Arthralgia	1 (16.7%)	2 (7.7%)	3 (10.3%)	6 (9.8%)
Bone pain		2 (7.7%)	2 (6.9%)	4 (6.6%)
Investigations	3 (50.0%)	12 (46.2%)	23 (79.3%)	38 (62.3%)
Alanine aminotransferase increased	1 (16.7%)	1 (3.8%)	12 (41.4%)	14 (23.0%)
Aspartate aminotransferase increased	2 (33.3%)	2 (7.7%)	10 (34.5%)	14 (23.0%)
Fibrin D dimer increased		5 (19.2%)	9 (31.0%)	14 (23.0%)
Gamma-glutamyltransferase increased	3 (50.0%)	1 (3.8%)	10 (34.5%)	14 (23.0%)
Blood alkaline phosphatase increased	2 (33.3%)	3 (11.5%)	8 (27.6%)	13 (21.3%)
Platelet count decreased	1 (16.7%)	3 (11.5%)	5 (17.2%)	9 (14.8%)
Activated partial thromboplastin		2 (7.7%)	5 (17.2%)	7 (11.5%)
Blood bilirubin increased	1 (16.7%)	1 (3.8%)	3 (10.3%)	5 (8.2%)
International normalised ratio increased	1 (16.7%)	1 (3.8%)	3 (10.3%)	5 (8.2%)
Lymphocyte count decreased		2 (7.7%)	2 (6.9%)	4 (6.6%)
Transaminases increased		2 (7.7%)	2 (6.9%)	4 (6.6%)
Metabolism and nutrition disorders	3 (50.0%)	18 (69.2%)	17 (58.6%)	38 (62.3%)
Decreased appetite	3 (50.0%)	13 (50.0%)	12 (41.4%)	28 (45.9%)
Hypophosphataemia		4 (15.4%)	4 (13.8%)	8 (13.1%)
Hypocalcaemia		3 (11.5%)	4 (13.8%)	7 (11.5%)
Hypoalbuminaemia		1 (3.8%)	3 (10.3%)	4 (6.6%)
Respiratory, thoracic and mediastinal disorders	1 (16.7%)	14 (53.8%)	15 (51.7%)	30 (49.2%)
Dyspnoea	1 (16.7%)	6 (23.1%)	7 (24.1%)	14 (23.0%)
Cough		5 (19.2%)	5 (17.2%)	10 (16.4%)
Hypoxia		1 (3.8%)	5 (17.2%)	6 (9.8%)
Blood and lymphatic system disorders	1 (16.7%)	9 (34.6%)	19 (65.5%)	29 (47.5%)

Counts and percentages represent the number and percentage of subjects with the event respectively.

N = Number of subjects; MedDRA = Medical Dictionary for Regulatory Activities
vp = viral particles

Table 17
Treatment-Emergent Adverse Events Occurring in at Least 5% of the Subjects
Safety Analysis Set

MedDRA (V19.1) System Organ Class Preferred Term	Initial Dose Level Assigned			All dosing groups (N = 61)
	< 1 x 10 ¹² vp (N = 6)	1 - 3 x 10 ¹² vp (N = 26)	> 3 x 10 ¹² vp (N = 29)	
Anaemia	1 (16.7%)	6 (23.1%)	9 (31.0%)	16 (26.2%)
Thrombocytopenia		2 (7.7%)	9 (31.0%)	11 (18.0%)
Neutropenia		1 (3.8%)	5 (17.2%)	6 (9.8%)
Infections and infestations	2 (33.3%)	9 (34.6%)	10 (34.5%)	21 (34.4%)
Nasopharyngitis	1 (16.7%)		4 (13.8%)	5 (8.2%)
Vascular disorders	1 (16.7%)	9 (34.6%)	10 (34.5%)	20 (32.8%)
Hypertension	1 (16.7%)	7 (26.9%)	7 (24.1%)	15 (24.6%)
Hypotension		2 (7.7%)	5 (17.2%)	7 (11.5%)
Nervous system disorders		7 (26.9%)	9 (31.0%)	16 (26.2%)
Headache		5 (19.2%)	5 (17.2%)	10 (16.4%)
Dizziness		3 (11.5%)	1 (3.4%)	4 (6.6%)
Renal and urinary disorders		9 (34.6%)	7 (24.1%)	16 (26.2%)
Proteinuria		5 (19.2%)	5 (17.2%)	10 (16.4%)
Acute kidney injury		1 (3.8%)	3 (10.3%)	4 (6.6%)
Psychiatric disorders	1 (16.7%)	2 (7.7%)	9 (31.0%)	12 (19.7%)
Insomnia		1 (3.8%)	5 (17.2%)	6 (9.8%)
Anxiety			4 (13.8%)	4 (6.6%)
Skin and subcutaneous tissue disorders		5 (19.2%)	6 (20.7%)	11 (18.0%)
Rash		2 (7.7%)	3 (10.3%)	5 (8.2%)
Pruritus		3 (11.5%)	1 (3.4%)	4 (6.6%)
Cardiac disorders		3 (11.5%)	3 (10.3%)	6 (9.8%)
Tachycardia		3 (11.5%)	2 (6.9%)	5 (8.2%)

Counts and percentages represent the number and percentage of subjects with the event respectively.
N = Number of subjects; MedDRA = Medical Dictionary for Regulatory Activities
vp = viral particles