

Supplemental Table 1. Treatment-related adverse events

Category	AE	N=230 Seviproimut-L				N=117 Placebo				N=347 Total				# (%) any grade
		G1	G2	G3	G4	G1	G2	G3	G4	G1	G2	G3	G4	
* Participant MAXIMUM grade*	****													245 (71%)
BLOOD/LYMPHATIC	ANY	4				1						5		5 (1%)
	ANEMIA	1				1					2			2 (<1%)
	LYMPHADENOPATHY	2									2			2 (<1%)
	LEUKOPENIA	1									1			1 (<1%)
	NEUTROPENIA	1									1			1 (<1%)
	THROMBOCYTOPENIA	1									1			1 (<1%)
CARDIAC	ANY	1									1			1 (<1%)
	BRADYCARDIA	1									1			1 (<1%)
EAR & LABYRINTH	ANY	1				1					2			2 (<1%)
	VERTIGO	1				1					2			2 (<1%)
EYE DISORDERS	ANY	6				3					9			9 (3%)
	DRY EYE	3									3			3 (1%)
	VISION BLURRED	2				1					3			3 (1%)
	DIPLOPIA	2									2			2 (<1%)
	OCULAR HYPEREMIA	2									2			2 (<1%)
	BLEPHARITIS					1								1 (<1%)
	CATARACT NUCLEAR	1									1			1 (<1%)
	EYE IRRITATION	1									1			1 (<1%)
	EYELID PTOSIS	1									1			1 (<1%)
	LACRIMATION INCREASED	1									1			1 (<1%)
	PHOTOPHOBIA	1									1			1 (<1%)
	PHOTOPSIA					1					1			1 (<1%)
	VISUAL IMPAIRMENT	1									1			1 (<1%)
	VITREOUS FLOATERS	1									1			1 (<1%)
GASTROINTESTINAL	ANY	23	1			9	1				32	2		34 (10%)
	ABDOMINAL DISCOMFORT	1									1			1 (<1%)
	APHTHOUS ULCER	1									1			1 (<1%)
	CONSTIPATION	1									1			1 (<1%)
	DIARRHEA	5				6					11			11 (3%)
	GASTROINTESTINAL PAIN	1									1			1 (<1%)
	GASTROINTESTINAL REFLUX DZ					1					1			1 (<1%)
	GINGIVAL PAIN	1									1			1 (<1%)
	GINGIVAL ULCERATION	1									1			1 (<1%)
	HEMATOCHEZIA	1									1			1 (<1%)
	NAUSEA	13	1			4	1				17	2		19 (5%)
	PARESTHEIAS, ORAL	1									1			1 (<1%)
	SALIVARY DUCT INFLAMMATION	2									2			2 (<1%)
	STOMATITIS					1					1			1 (<1%)
	VOMITING	2				2					4			4 (1%)
GENERAL AND ADMINISTRATION SITE	ANY	130	14			68	5				198	19		217 (63%)
	ASTHENIA	1									1			1 (<1%)
	AXILLARY PAIN	1									1			1 (<1%)
	CHILLS	4									4			4 (1%)
	EDEMA, PERIPHERAL	2									2			2 (<1%)
	FATIGUE	34	8			23	3				57	11		68 (20%)
	FEELING HOT	2									2			2 (<1%)
	FEVER (PYREXIA)	3				3					6			6 (2%)
	INFLUENZA LIKE ILLNESS	6	3			3					9	3		12 (3%)
	INJECTION SITE BRUISING	12				6					18			18 (5%)
	INJECTION SITE DISCOMFORT					2					2			2 (<1%)
	INJECTION SITE DISCOLORATION	7				3					10			10 (3%)
	INJECTION SITE EDEMA	1									1			1 (<1%)
	INJECTION SITE ERYTHEMA	72	1			48					120	1		121 (35%)
	INJECTION SITE GRANULOMA	1									1			1 (<1%)
	INJECTION SITE HEMORRHAGE	3				1					4			4 (1%)
	INJECTION SITE HYPERESTHESIA	1									1			1 (<1%)
	INJECTION SITE HYPERTROPHY	1									1			1 (<1%)
	INJECTION SITE INDURATION	9				3					12			12 (3%)
	INJECTION SITE INFLAMMATION	1									1			1 (<1%)
	INJECTION SITE IRRITATION					3					3			3 (1%)
	INJECTION SITE MACULE	1									1			1 (<1%)

Category	AE	N=230 Seviproimut-L				N=117 Placebo				N=347 Total				# (%) any grade G1 – G4
		G1	G2	G3	G4	G1	G2	G3	G4	G1	G2	G3	G4	
	INJECTION SITE MASS	1								1				1 (<1%)
	INJECTION SITE NODULE	8				2				10				10 (3%)
	INJECTION SITE PAIN	29	2			12	1			41	3			44 (13%)
	INJECTION SITE PAPULE	3								3				3 (1%)
	INJECTION SITE PRURITIS	44	2			13	1			57	3			60 (17%)
	INJECTION SITE RASH	8				3				11				11 (3%)
	INJECTION SITE REACTION	2								2				2 (<1%)
	INJECTION SITE SWELLING	15				6				21				21 (6%)
	INJECTION SITE URTICARIA	5								5				5 (1%)
	INJECTION SITE WARMTH	1				1				2				2 (<1%)
	MALaise	1				1				2				2 (<1%)
	SWELLING	1								1				1 (<1%)
	PAIN	5								5				5 (1%)
	VACCINATION SITE PRURITIS					1				1				1 (<1%)
IMMUNE SYSTEM	ANY	1								1				1 (<1%)
	IODINE ALLERGY	1								1				1 (<1%)
INFECTIONS/INFESTATIONS	ANY	2	1			1	2			3	3			6 (2%)
	CELLULITIS						1				1			1 (<1%)
	EAR INFECTION						1				1			1 (<1%)
	KIDNEY INFECTION					1					1			1 (<1%)
	NASOPHARYNGITIS	1								1				1 (<1%)
	TINEA VERSICOLOR	1								1				1 (<1%)
	URINARY TRACT INFECTION		1								1			1 (<1%)
INJURY/POISONING/PROCEDURAL	ANY					1				1				1 (<1%)
	CONTUSION					1				1				1 (<1%)
INVESTIGATIONS	ANY	3	2			3				6	2			8 (2%)
	ALT INCREASED	1	1			2				3	1			4 (1%)
	AST INCREASED	1				2				3				3 (1%)
	BILIRUBIN INCREASED		1								1			1 (<1%)
	CREATININE INCREASED					2				2				2 (<1%)
	GGT INCREASED	1								1				1 (<1%)
	TESTOSTERONE DECREASED	2				2				2				2 (<1%)
	UREA INCREASED					1				1				1 (<1%)
METABOLISM/NUTRITION	ANY	5				1	1			6	1			7 (2%)
	DECREASED APPETITE	2				1				3				3 (1%)
	GLUCOSE TOLERANCE IMPAIRED	1								1				1 (<1%)
	HYPOCALCEMIA	1								1				1 (<1%)
	HYPOGLYCEMIA	1								1				1 (<1%)
	HYPONATREMIA	1								1				1 (<1%)
	HYPOPHOSPHATEMIA						1				1			1 (<1%)
MUSCULOSKELETAL/CONNECTIVE TISSUE	ANY	16	4			11	1			27	5			32 (9%)
	ARTHRALGIA	2	2			5				7	2			9 (3%)
	ARTHRITIS	1	1							1	1			2 (<1%)
	BACK PAIN					1				1				1 (<1%)
	BONE PAIN	1								1				1 (<1%)
	GROIN PAIN	2								2				2 (<1%)
	MUSCLE SPASMS		1			1				1	1			2 (<1%)
	MUSCULAR WEAKNESS					2				2				2 (<1%)
	MUSCLOSKELETAL PAIN	1								1				1 (<1%)
	MYALGIA	9				4	1			13	1			14 (4%)
	NECK PAIN	1								1				1 (<1%)
	PAIN IN EXTREMITY	3				1				4				4 (1%)
	SOFT TISSUE DISORDER	1								1				1 (<1%)
NEOPLASMS	ANY		1			1	1			1	2			3 (1%)
	DYSPLASTIC NEVUS	1								1				1 (<1%)
	HEMANGIOMA OF SKIN	1								1				1 (<1%)
	LIP SQUAMOUS CELL CA	1								1				1 (<1%)
	MELANOCYTIC NEVUS					1	1			1	1			2 (<1%)
	SEBORRHEIC KERATOSIS	1								1				1 (<1%)
	SQUAMOUS CELL CA OF SKIN	1								1				1 (<1%)
NERVOUS SYSTEM	ANY	19	2	1		16				35	2	1		38 (11%)
	DISTURBANCE IN ATTENTION					1				1				1 (<1%)
	DIZZINESS	2				1				3				3 (1%)
	DYSGEUSIA	4				1				5				5 (1%)
	HEADACHE	13	2	1		12				25	2	1		28 (8%)
	MEMORY IMPAIRMENT					1				1				1 (<1%)

Category	AE	N=230 Seviproimut-L				N=117 Placebo				N=347 Total			# (%) any grade	
		G1	G2	G3	G4	G1	G2	G3	G4	G1	G2	G3		G4
	NEUROPATHY, PERIPHERAL	1				1				2				2 (<1%)
	PARESTHESIA	1				1				2				2 (<1%)
PSYCHIATRIC DISORDERS	ANY	6				2				8				8 (2%)
	AGITATION	1								1				1 (<1%)
	ANXIETY					1				1				1 (<1%)
	DEPRESSION					1				1				1 (<1%)
	INSOMNIA	4				1				5				5 (1%)
	IRRITABILITY	1								1				1 (<1%)
RENAL AND URINARY	ANY					1				1				1 (<1%)
	NEPHROLITHIASIS					1				1				1 (<1%)
REPRODUCTIVE AND BREAST	ANY	2								2				2 (<1%)
	BREAST DISCOLORATION	1								1				1 (<1%)
	MENSTRUATION, IRREGULAR	1								1				1 (<1%)
RESPIRATORY/THORACIC/MEDIASTINAL	ANY	3	2			2				5	2			7 (2%)
	ASTHMA		1								1			1 (<1%)
	COUGH		1								1			1 (<1%)
	NASAL CONGESTION					1				1				1 (<1%)
	NASAL ULCER	1								1				1 (<1%)
	PRODUCTIVE COUGH					1				1				1 (<1%)
	RHINALGIA					1				1				1 (<1%)
	RHINORRHEA	2								2				2 (<1%)
SKIN/SUBCUTANEOUS TISSUE	ANY	27	6	3		17	4			44	10	3		57 (16%)
	ACNE	1					1			2				2 (<1%)
	ALOPECIA	1				1				2				2 (<1%)
	BLISTER	1	1							1	1			2 (<1%)
	DERMATITIS ACNEIFORM	2					1			2	1			3 (1%)
	DERMATITIS, ALLERGIC		2								2			2 (<1%)
	ECZEMA		2								2			2 (<1%)
	ERYTHEMA	3								3				3 (1%)
	LENTIGO	1								1				1 (<1%)
	KERATOTIS PILARIS					1				1				1 (<1%)
	NIGHT SWEATS					1				1				1 (<1%)
	NEURODERMATITIS		1				1			1	1			2 (<1%)
	PANNICULITIS	1								1				1 (<1%)
	PIGMENTATION DISORDER	1								1				1 (<1%)
	PHOTOSENSITIVITY REACTION	1	1							1	1			2 (<1%)
	PRURITUS	11	2			5				16	2			18 (5%)
	PRURITUS, GENERALIZED	1								1				1 (<1%)
	RASH	7		1		4	2			11	2	1		14 (4%)
	RASH ERYTHEMATOUS	2					1			2	1			3 (1%)
	RASH, GENERALIZED	1								1				1 (<1%)
	RASH MACULAR			2							2			2 (<1%)
	RASH MACULO-PAPULAR	3				4				7				7 (2%)
	RASH PAPULAR	2				2				4				4 (1%)
	RASH PRURITIC	2				1				3				3 (1%)
	SCAR PAIN					1				1				1 (<1%)
	SEBORRHEIC DERMATITIS					1				1				1 (<1%)
	SKIN DEPIGMENTATION	1								1				1 (<1%)
	SKIN HYPOPIGMENTATION	1								1				1 (<1%)
	SKIN IRRITATION		1								1			1 (<1%)
	SKIN ULCERATION	1								1				1 (<1%)
	URTICARIA	2								2				2 (<1%)
	VITILIGO					2				2				2 (<1%)
VASCULAR	ANY	1				1				2				2 (<1%)
	HOT FLUSH	1								1				1 (<1%)
	LYMPHEDEMA					1				1				1 (<1%)