

Table 2: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo		Xanomeline	Xanomeline	Total (N=254)
		n	(%)	Low Dose (N=96)	High Dose (N=72)	
ANY EVENT	ANY EVENT	69	(80%)	86	(90%)	70 (97%) 225 (89%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	ANY EVENT	0	(0%)	1	(1%)	2 (3%) 3 (1%)
	VENTRICULAR SEPTAL DEFECT	0	(0%)	1	(1%)	2 (3%) 3 (1%)
EAR AND LABYRINTH DISORDERS	ANY EVENT	1	(1%)	2	(2%)	1 (1%) 4 (2%)
	CERUMEN IMPACTION	0	(0%)	1	(1%)	0 (0%) 1 (0%)
	EAR PAIN	1	(1%)	0	(0%)	0 (0%) 1 (0%)
	TINNITUS	0	(0%)	1	(1%)	0 (0%) 1 (0%)
	VERTIGO	0	(0%)	1	(1%)	1 (1%) 2 (1%)
EYE DISORDERS	ANY EVENT	4	(5%)	2	(2%)	1 (1%) 7 (3%)
	CONJUNCTIVAL HAEMORRHAGE	0	(0%)	1	(1%)	0 (0%) 1 (0%)
	CONJUNCTIVITIS	2	(2%)	0	(0%)	0 (0%) 2 (1%)
	EYE ALLERGY	1	(1%)	0	(0%)	0 (0%) 1 (0%)
	EYE PRURITUS	1	(1%)	0	(0%)	0 (0%) 1 (0%)
	EYE SWELLING	1	(1%)	0	(0%)	0 (0%) 1 (0%)
	GLAUCOMA	1	(1%)	0	(0%)	0 (0%) 1 (0%)
	VISION BLURRED	0	(0%)	1	(1%)	1 (1%) 2 (1%)

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			Low Dose (N=96)	High Dose (N=72)	
GASTROINTESTINAL DISORDERS	ANY EVENT	17 (20%)	16 (17%)	20 (28%)	53 (21%)
	ABDOMINAL DISCOMFORT	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	ABDOMINAL PAIN	1 (1%)	3 (3%)	1 (1%)	5 (2%)
	CONSTIPATION	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	DIARRHOEA	9 (10%)	6 (6%)	3 (4%)	18 (7%)
	DYSPEPSIA	1 (1%)	1 (1%)	1 (1%)	3 (1%)
	DYSPHAGIA	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	FLATULENCE	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	GASTROINTESTINAL	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	HAEMORRHAGE				
	GASTROOESOPHAGEAL REFLUX DISEASE	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	GLOSSITIS	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	HIATUS HERNIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	NAUSEA	3 (3%)	3 (3%)	6 (8%)	12 (5%)
	RECTAL HAEMORRHAGE	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	SALIVARY HYPERSECRETION	0 (0%)	0 (0%)	4 (6%)	4 (2%)
	STOMACH DISCOMFORT	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	VOMITING	3 (3%)	4 (4%)	6 (8%)	13 (5%)
HEPATOBILIARY DISORDERS	ANY EVENT	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	HYPERBILIRUBINAEMIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)

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		Placebo (N=86)	Low Dose (N=96)	High Dose (N=72)	n (%)	
IMMUNE SYSTEM DISORDERS	ANY EVENT	0 (0%)	1 (1%)	1 (1%)	2 (1%)	
	HYPERSENSITIVITY	0 (0%)	1 (1%)	0 (0%)	1 (0%)	
	SEASONAL ALLERGY	0 (0%)	0 (0%)	1 (1%)	1 (0%)	

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		Placebo (N=86)	Low Dose (N=96)	High Dose (N=72)	n (%)	
INFECTIONS AND INFESTATIONS	ANY EVENT	16 (19%)	10 (10%)	13 (18%)	39 (15%)	
	BRONCHITIS	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	CELLULITIS	0 (0%)	1 (1%)	0 (0%)	1 (0%)	
	CERVICITIS	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	CYSTITIS	1 (1%)	0 (0%)	1 (1%)	2 (1%)	
	EAR INFECTION	2 (2%)	0 (0%)	0 (0%)	2 (1%)	
	GASTROENTERITIS VIRAL	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	HORDEOLUM	0 (0%)	0 (0%)	1 (1%)	1 (0%)	
	INFLUENZA	1 (1%)	1 (1%)	1 (1%)	3 (1%)	
	LOCALISED INFECTION	1 (1%)	1 (1%)	0 (0%)	2 (1%)	
	LOWER RESPIRATORY TRACT INFECTION	0 (0%)	0 (0%)	1 (1%)	1 (0%)	
	NASOPHARYNGITIS	2 (2%)	4 (4%)	6 (8%)	12 (5%)	
	ONYCHOMYCOSIS	0 (0%)	1 (1%)	0 (0%)	1 (0%)	
	PNEUMONIA	0 (0%)	1 (1%)	0 (0%)	1 (0%)	
	RHINITIS	0 (0%)	0 (0%)	1 (1%)	1 (0%)	
	UPPER RESPIRATORY TRACT INFECTION	6 (7%)	1 (1%)	3 (4%)	10 (4%)	
	URINARY TRACT INFECTION	2 (2%)	0 (0%)	1 (1%)	3 (1%)	
	VAGINAL MYCOSIS	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	VIRAL INFECTION	0 (0%)	1 (1%)	0 (0%)	1 (0%)	

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		n	(%)	Low Dose (N=96)	High Dose (N=72)	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ANY EVENT	4	(5%)	5	(5%)	14 (6%)
	CONTUSION	1	(1%)	1	(1%)	2 (3%)
	EXCORIATION	2	(2%)	1	(1%)	1 (1%)
	FACIAL BONES FRACTURE	0	(0%)	0	(0%)	1 (0%)
	FALL	1	(1%)	2	(2%)	1 (1%)
	HIP FRACTURE	1	(1%)	0	(0%)	2 (3%)
	JOINT DISLOCATION	0	(0%)	1	(1%)	0 (0%)
	SKIN LACERATION	1	(1%)	2	(2%)	0 (0%)
	WOUND	0	(0%)	1	(1%)	1 (0%)
METABOLISM AND NUTRITION DISORDERS	ANY EVENT	6	(7%)	1	(1%)	3 (4%)
	DECREASED APPETITE	1	(1%)	0	(0%)	1 (1%)
	DEHYDRATION	1	(1%)	0	(0%)	0 (0%)
	DIABETES MELLITUS	1	(1%)	0	(0%)	0 (0%)
	FOOD CRAVING	1	(1%)	1	(1%)	0 (0%)
	HYPERCHOLESTEROLAEMIA	0	(0%)	0	(0%)	1 (1%)
	HYPONATRAEMIA	1	(1%)	0	(0%)	0 (0%)
	INCREASED APPETITE	1	(1%)	0	(0%)	1 (1%)

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MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ANY EVENT	5 (6%)	7 (7%)	8 (11%)	20 (8%)
	ARTHRALGIA	1 (1%)	2 (2%)	1 (1%)	4 (2%)
	ARTHRITIS	1 (1%)	0 (0%)	1 (1%)	2 (1%)
	BACK PAIN	1 (1%)	1 (1%)	3 (4%)	5 (2%)
	FLANK PAIN	0 (0%)	0 (0%)	2 (3%)	2 (1%)
	MUSCLE SPASMS	0 (0%)	1 (1%)	1 (1%)	2 (1%)
	MUSCULAR WEAKNESS	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	MYALGIA	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	PAIN IN EXTREMITY	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	SHOULDER PAIN	1 (1%)	2 (2%)	0 (0%)	3 (1%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ANY EVENT	0 (0%)	2 (2%)	1 (1%)	3 (1%)
	COLON CANCER	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	MALIGNANT FIBROUS HISTIOCYTOMA	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	PROSTATE CANCER	0 (0%)	0 (0%)	1 (1%)	1 (0%)

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		Placebo (N=86)	Low Dose (N=96)	High Dose (N=72)	n (%)	
PSYCHIATRIC DISORDERS	ANY EVENT	10 (12%)	11 (11%)	8 (11%)	29 (11%)	
	AGITATION	2 (2%)	3 (3%)	0 (0%)	5 (2%)	
	ANXIETY	1 (1%)	3 (3%)	0 (0%)	4 (2%)	
	COMPLETED SUICIDE	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	CONFUSIONAL STATE	2 (2%)	3 (3%)	1 (1%)	6 (2%)	
	DELIRIUM	0 (0%)	0 (0%)	1 (1%)	1 (0%)	
	DELUSION	1 (1%)	0 (0%)	1 (1%)	2 (1%)	
	DEPRESSED MOOD	0 (0%)	1 (1%)	1 (1%)	2 (1%)	
	DISORIENTATION	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	HALLUCINATION	0 (0%)	0 (0%)	1 (1%)	1 (0%)	
	HALLUCINATION, VISUAL	0 (0%)	0 (0%)	1 (1%)	1 (0%)	
	INSOMNIA	2 (2%)	0 (0%)	2 (3%)	4 (2%)	
	IRRITABILITY	1 (1%)	1 (1%)	0 (0%)	2 (1%)	
	LIBIDO DECREASED	0 (0%)	0 (0%)	1 (1%)	1 (0%)	
	LISTLESS	0 (0%)	0 (0%)	1 (1%)	1 (0%)	
	NIGHTMARE	0 (0%)	0 (0%)	1 (1%)	1 (0%)	
	RESTLESSNESS	0 (0%)	1 (1%)	0 (0%)	1 (0%)	

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RENAL AND URINARY DISORDERS	ANY EVENT	4	(5%)	4	(4%)	3 (4%)
	CALCULUS URETHRAL	0	(0%)	0	(0%)	1 (1%)
	DYSURIA	1	(1%)	1	(1%)	0 (0%)
	ENURESIS	0	(0%)	1	(1%)	0 (0%)
	INCONTINENCE	0	(0%)	1	(1%)	0 (0%)
	MICTURITION URGENCY	1	(1%)	1	(1%)	1 (1%)
	NEPHROLITHIASIS	1	(1%)	0	(0%)	1 (1%)
	POLLAKIURIA	1	(1%)	0	(0%)	1 (0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ANY EVENT	2	(2%)	0	(0%)	1 (1%)
	BENIGN PROSTATIC HYPERPLASIA	1	(1%)	0	(0%)	1 (1%)
	PELVIC PAIN	1	(1%)	0	(0%)	0 (0%)
						1 (0%)

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RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ANY EVENT	10	(12%)	10	(10%)	10	(14%)	30	(12%)
	ALLERGIC GRANULOMATOUS ANGIITIS	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	COUGH	3	(3%)	6	(6%)	5	(7%)	14	(6%)
	DYSPHONIA	0	(0%)	1	(1%)	0	(0%)	1	(0%)
	DYSPNOEA	1	(1%)	1	(1%)	1	(1%)	3	(1%)
	EMPHYSEMA	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	EPISTAXIS	0	(0%)	1	(1%)	2	(3%)	3	(1%)
	HAEMOPTYSIS	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	NASAL CONGESTION	3	(3%)	1	(1%)	3	(4%)	7	(3%)
	PHARYNGEAL ERYTHEMA	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	PHARYNGOLARYNGEAL PAIN	0	(0%)	1	(1%)	1	(1%)	2	(1%)
	POSTNASAL DRIP	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	PRODUCTIVE COUGH	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	RALES	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	RESPIRATORY TRACT CONGESTION	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	RHINORRHOEA	0	(0%)	1	(1%)	1	(1%)	2	(1%)
SOCIAL CIRCUMSTANCES	ANY EVENT	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	ALCOHOL USE	0	(0%)	0	(0%)	1	(1%)	1	(0%)

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		n	(%)	n	(%)	n	(%)
SURGICAL AND MEDICAL PROCEDURES	ANY EVENT	2	(2%)	1	(1%)	2	(3%)
	ACROCHORDON EXCISION	0	(0%)	0	(0%)	1	(1%)
	CATARACT OPERATION	1	(1%)	1	(1%)	0	(0%)
	EYE LASER SURGERY	1	(1%)	0	(0%)	0	(0%)
	SKIN LESION EXCISION	0	(0%)	0	(0%)	1	(1%)
VASCULAR DISORDERS	ANY EVENT	3	(3%)	4	(4%)	1	(1%)
	HOT FLUSH	0	(0%)	1	(1%)	0	(0%)
	HYPERTENSION	1	(1%)	2	(2%)	0	(0%)
	HYPOTENSION	2	(2%)	1	(1%)	0	(0%)
	ORTHOSTATIC HYPOTENSION	1	(1%)	0	(0%)	0	(0%)
	WOUND HAEMORRHAGE	0	(0%)	0	(0%)	1	(1%)

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