

Table 2: Summary of Treatment Emergent Adverse Events

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

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Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	High Dose	High Dose	Total	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
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	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	DISEASE						
	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%)		
HEPATOBIILIARY DISORDERS	ANY EVENT	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	HYPERBILIRUBINAEMIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)		

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Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	(N=96)	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
IMMUNE SYSTEM DISORDERS	ANY EVENT	0 (0%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)
	HYPERSENSITIVITY	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
	SEASONAL ALLERGY	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (1%)	1 (0%)

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		(N=86)	Low Dose	High Dose	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	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=86)	Low Dose	High Dose	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ANY EVENT	4 (5%)	5 (5%)	5 (7%)	5 (7%)	5 (7%)	14 (6%)
	CONTUSION	1 (1%)	1 (1%)	2 (3%)	2 (3%)	2 (3%)	4 (2%)
	EXCORIATION	2 (2%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	4 (2%)
	FACIAL BONES FRACTURE	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (1%)	1 (0%)
	FALL	1 (1%)	2 (2%)	1 (1%)	1 (1%)	1 (1%)	4 (2%)
	HIP FRACTURE	1 (1%)	0 (0%)	2 (3%)	2 (3%)	2 (3%)	3 (1%)
	JOINT DISLOCATION	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
	SKIN LACERATION	1 (1%)	2 (2%)	0 (0%)	0 (0%)	0 (0%)	3 (1%)
	WOUND	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
METABOLISM AND NUTRITION DISORDERS	ANY EVENT	6 (7%)	1 (1%)	3 (4%)	3 (4%)	3 (4%)	10 (4%)
	DECREASED APPETITE	1 (1%)	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)
	DEHYDRATION	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
	DIABETES MELLITUS	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
	FOOD CRAVING	1 (1%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)
	HYPERCHOLESTEROLAEMIA	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (1%)	1 (0%)
	HYPONATRAEMIA	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
	INCREASED APPETITE	1 (1%)	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)

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		(N=86)	Low Dose	High Dose	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ANY EVENT	5 (6%)	7 (7%)	8 (11%)	8 (11%)	20 (8%)	20 (8%)
	ARTHRALGIA	1 (1%)	2 (2%)	1 (1%)	1 (1%)	4 (2%)	4 (2%)
	ARTHRITIS	1 (1%)	0 (0%)	1 (1%)	1 (1%)	2 (1%)	2 (1%)
	BACK PAIN	1 (1%)	1 (1%)	3 (4%)	3 (4%)	5 (2%)	5 (2%)
	FLANK PAIN	0 (0%)	0 (0%)	2 (3%)	2 (3%)	2 (1%)	2 (1%)
	MUSCLE SPASMS	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)	2 (1%)
	MUSCULAR WEAKNESS	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	MYALGIA	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)
	PAIN IN EXTREMITY	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SHOULDER PAIN	1 (1%)	2 (2%)	0 (0%)	0 (0%)	3 (1%)	3 (1%)
	ANY EVENT	0 (0%)	2 (2%)	1 (1%)	1 (1%)	3 (1%)	3 (1%)
	COLON CANCER	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	MALIGNANT FIBROUS HISTIOCYTOMA	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	PROSTATE CANCER	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)

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		n (%)	n (%)	n (%)	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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		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
RENAL AND URINARY DISORDERS	ANY EVENT	4 (5%)	4 (4%)	3 (4%)	3 (4%)	3 (4%)	11 (4%)
	CALCULUS URETHRAL	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (1%)	1 (0%)
	DYSURIA	1 (1%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)
	ENURESIS	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
	INCONTINENCE	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
	MICTURITION URGENCY	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	3 (1%)
	NEPHROLITHIASIS	1 (1%)	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)
	POLLAKIURIA	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ANY EVENT	2 (2%)	0 (0%)	1 (1%)	1 (1%)	1 (1%)	3 (1%)
	BENIGN PROSTATIC HYPERPLASIA	1 (1%)	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)
	PELVIC PAIN	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)

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		(N=86)	Low Dose	(N=96)	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
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 (%)	n (%)	n (%)	n (%)
SURGICAL AND MEDICAL PROCEDURES	ANY EVENT	2 (2%)	1 (1%)	2 (3%)	2 (3%)	5 (2%)	5 (2%)
	ACROCHORDON EXCISION	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)
	CATARACT OPERATION	1 (1%)	1 (1%)	0 (0%)	0 (0%)	2 (1%)	2 (1%)
	EYE LASER SURGERY	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	SKIN LESION EXCISION	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)
VASCULAR DISORDERS	ANY EVENT	3 (3%)	4 (4%)	1 (1%)	1 (1%)	8 (3%)	8 (3%)
	HOT FLUSH	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	HYPERTENSION	1 (1%)	2 (2%)	0 (0%)	0 (0%)	3 (1%)	3 (1%)
	HYPOTENSION	2 (2%)	1 (1%)	0 (0%)	0 (0%)	3 (1%)	3 (1%)
	ORTHOSTATIC HYPOTENSION	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	WOUND HAEMORRHAGE	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)

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