Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
At least one TEAE	77 (91.7)	412	76 (90.5)	433	65 (75.6)	281
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	47 (56.0)	118	40 (47.6)	124	21 (24.4)	46
APPLICATION SITE PRURITUS	22 (26.2)	32	22 (26.2)	35	6 (7.0)	10
APPLICATION SITE ERYTHEMA	12 (14.3)	20	15 (17.9)	23	3 (3.5)	3
APPLICATION SITE DERMATITIS	9 (10.7)	15	7 (8.3)	12	5 (5.8)	9
APPLICATION SITE IRRITATION	9 (10.7)	18	9 (10.7)	16	3 (3.5)	7
APPLICATION SITE VESICLES	4 (4.8)	5	6 (7.1)	6	1 (1.2)	2
FATIGUE	5 (6.0)	5	5 (6.0)	5	1 (1.2)	2
OEDEMA PERIPHERAL	1 (1.2)	1	2 (2.4)	3	2 (2.3)	3
APPLICATION SITE SWELLING	1 (1.2)	1	2 (2.4)	3	0	0
APPLICATION SITE URTICARIA	2 (2.4)	2	1 (1.2)	1	0	0
CHILLS	1 (1.2)	2	1 (1.2)	1	1 (1.2)	3
MALAISE	1 (1.2)	2	2 (2.4)	3	0	0
PYREXIA	0	0	1 (1.2)	1	2 (2.3)	2
APPLICATION SITE PAIN	0	0	2 (2.4)	2	0	0
APPLICATION SITE PERSPIRATION	0	0	2 (2.4)	3	0	0
APPLICATION SITE REACTION	0	0	1 (1.2)	1	1 (1.2)	2
ASTHENIA	0	0	1 (1.2)	1	1 (1.2)	2
CHEST DISCOMFORT	0	0	2 (2.4)	2	0	0
CHEST PAIN	0	0	2 (2.4)	2	0	0
OEDEMA	2 (2.4)	2	0	0	0	0
PAIN	1 (1.2)	2	1 (1.2)	1	0	0
APPLICATION SITE BLEEDING	1 (1.2)	1	0	0	0	0
APPLICATION SITE DESQUAMATION	1 (1.2)	1	0	0	0	0
APPLICATION SITE DISCHARGE	0	0	1 (1.2)	1	0	0
APPLICATION SITE DISCOLOURATION	1 (1.2)	1	0	0	0	0

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
APPLICATION SITE INDURATION	0	0	0	0	1 (1.2)	1
APPLICATION SITE WARMTH	1 (1.2)	2	0	0	0	0
FEELING ABNORMAL	0	0	1 (1.2)	1	0	0
FEELING COLD	0	0	1 (1.2)	1	0	0
INFLAMMATION	1 (1.2)	1	0	0	0	0
SECRETION DISCHARGE	1 (1.2)	2	0	0	0	0
SUDDEN DEATH	1 (1.2)	1	0	0	0	0
SWELLING	1 (1.2)	1	0	0	0	0
ULCER	1 (1.2)	1	0	0	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	39 (46.4)	111	40 (47.6)	104	20 (23.3)	45
PRURITUS	21 (25.0)	31	26 (31.0)	38	8 (9.3)	11
ERYTHEMA	14 (16.7)	22	14 (16.7)	22	8 (9.3)	12
RASH	13 (15.5)	18	9 (10.7)	15	5 (5.8)	9
HYPERHIDROSIS	4 (4.8)	5	8 (9.5)	10	2 (2.3)	2
SKIN IRRITATION	6 (7.1)	13	5 (6.0)	8	3 (3.5)	4
BLISTER	5 (6.0)	8	1 (1.2)	2	0	0
RASH PRURITIC	1 (1.2)	2	2 (2.4)	3	0	0
PRURITUS GENERALISED	1 (1.2)	4	1 (1.2)	1	0	0
URTICARIA	1 (1.2)	3	1 (1.2)	2	0	0
ACTINIC KERATOSIS	0	0	1 (1.2)	1	0	0
ALOPECIA	0	0	0	0	1 (1.2)	1
COLD SWEAT	0	0	0	0	1 (1.2)	3
DERMATITIS CONTACT	1 (1.2)	2	0	0	0	0
DRUG ERUPTION	0	0	0	0	1 (1.2)	1
RASH ERYTHEMATOUS	1 (1.2)	1	0	0	0	0
RASH MACULO-PAPULAR	0	0	1 (1.2)	1	0	0
SKIN EXFOLIATION	1 (1.2)	2	0	0	0	0

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
SKIN ODOUR ABNORMAL	0	0	1 (1.2)	1	0	0
SKIN ULCER	0	0	0	0	1 (1.2)	2
NERVOUS SYSTEM DISORDERS	20 (23.8)	40	25 (29.8)	41	8 (9.3)	11
DIZZINESS	8 (9.5)	13	11 (13.1)	15	2 (2.3)	3
HEADACHE	3 (3.6)	4	5 (6.0)	8	3 (3.5)	3
SYNCOPE	4 (4.8)	6	3 (3.6)	4	0	0
SOMNOLENCE	3 (3.6)	5	1 (1.2)	1	2 (2.3)	3
TRANSIENT ISCHAEMIC ATTACK	2 (2.4)	3	1 (1.2)	1	0	0
BURNING SENSATION	0	0	2 (2.4)	2	0	0
LETHARGY	1 (1.2)	1	1 (1.2)	1	0	0
AMNESIA	0	0	1 (1.2)	2	0	0
BALANCE DISORDER	1 (1.2)	3	0	0	0	0
COGNITIVE DISORDER	0	0	1 (1.2)	1	0	0
COMPLEX PARTIAL SEIZURES	1 (1.2)	1	0	0	0	0
COORDINATION ABNORMAL	1 (1.2)	1	0	0	0	0
HEMIANOPIA HOMONYMOUS	1 (1.2)	1	0	0	0	0
HYPERSOMNIA	0	0	1 (1.2)	1	0	0
PARAESTHESIA	0	0	1 (1.2)	1	0	0
PARAESTHESIA ORAL	1 (1.2)	1	0	0	0	0
PARKINSON'S DISEASE	0	0	0	0	1 (1.2)	1
PAROSMIA	0	0	1 (1.2)	2	0	0
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0	0	1 (1.2)	1	0	0
PSYCHOMOTOR HYPERACTIVITY	0	0	0	0	1 (1.2)	1
STUPOR	1 (1.2)	1	0	0	0	0
SYNCOPE VASOVAGAL	0	0	1 (1.2)	1	0	0
GASTROINTESTINAL DISORDERS	14 (16.7)	22	20 (23.8)	36	17 (19.8)	26

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
DIARRHOEA	4 (4.8)	5	4 (4.8)	4	9 (10.5)	10
VOMITING	3 (3.6)	4	7 (8.3)	9	3 (3.5)	3
NAUSEA	3 (3.6)	5	6 (7.1)	13	3 (3.5)	3
ABDOMINAL PAIN	3 (3.6)	3	1 (1.2)	2	1 (1.2)	1
SALIVARY HYPERSECRETION	0	0	4 (4.8)	5	0	0
DYSPEPSIA	1 (1.2)	2	0	0	1 (1.2)	2
ABDOMINAL DISCOMFORT	0	0	1 (1.2)	1	0	0
CONSTIPATION	0	0	0	0	1 (1.2)	1
DYSPHAGIA	1 (1.2)	1	0	0	0	0
FLATULENCE	0	0	0	0	1 (1.2)	2
GASTROINTESTINAL HAEMORRHAGE	0	0	1 (1.2)	1	0	0
GASTROOESOPHAGEAL REFLUX DISEASE	0	0	0	0	1 (1.2)	1
GLOSSITIS	0	0	0	0	1 (1.2)	1
HIATUS HERNIA	0	0	0	0	1 (1.2)	2
RECTAL HAEMORRHAGE	1 (1.2)	2	0	0	0	0
STOMACH DISCOMFORT	0	0	1 (1.2)	1	0	0
CARDIAC DISORDERS	13 (15.5)	30	15 (17.9)	30	12 (14.0)	26
SINUS BRADYCARDIA	7 (8.3)	10	8 (9.5)	12	2 (2.3)	2
MYOCARDIAL INFARCTION	2 (2.4)	4	4 (4.8)	8	4 (4.7)	4
ATRIAL FIBRILLATION	1 (1.2)	1	3 (3.6)	5	1 (1.2)	1
SUPRAVENTRICULAR EXTRASYSTOLES	1 (1.2)	2	1 (1.2)	1	1 (1.2)	2
VENTRICULAR EXTRASYSTOLES	2 (2.4)	4	1 (1.2)	1	0	0
ATRIAL FLUTTER	1 (1.2)	1	1 (1.2)	2	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 (1.2)	1	0	0	1 (1.2)	1
BUNDLE BRANCH BLOCK RIGHT	1 (1.2)	1	0	0	1 (1.2)	2
PALPITATIONS	2 (2.4)	2	0	0	0	0
ATRIAL HYPERTROPHY	0	0	0	0	1 (1.2)	2

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
ATRIOVENTRICULAR BLOCK SECOND DEGREE	0	0	0	0	1 (1.2)	1
BRADYCARDIA	0	0	0	0	1 (1.2)	4
BUNDLE BRANCH BLOCK LEFT	0	0	0	0	1 (1.2)	1
CARDIAC DISORDER	0	0	1 (1.2)	1	0	0
CARDIAC FAILURE CONGESTIVE	0	0	0	0	1 (1.2)	1
SINUS ARRHYTHMIA	0	0	0	0	1 (1.2)	2
SUPRAVENTRICULAR TACHYCARDIA	1 (1.2)	2	0	0	0	0
TACHYCARDIA	0	0	0	0	1 (1.2)	2
VENTRICULAR HYPERTROPHY	0	0	0	0	1 (1.2)	1
WOLFF-PARKINSON-WHITE SYNDROME	1 (1.2)	2	0	0	0	0
INFECTIONS AND INFESTATIONS	9 (10.7)	16	13 (15.5)	20	16 (18.6)	35
NASOPHARYNGITIS	4 (4.8)	9	6 (7.1)	8	2 (2.3)	4
UPPER RESPIRATORY TRACT INFECTION	1 (1.2)	2	3 (3.6)	5	6 (7.0)	12
INFLUENZA	1 (1.2)	1	1 (1.2)	1	1 (1.2)	2
URINARY TRACT INFECTION	0	0	1 (1.2)	1	2 (2.3)	4
CYSTITIS	0	0	1 (1.2)	1	1 (1.2)	1
EAR INFECTION	0	0	0	0	2 (2.3)	4
BRONCHITIS	0	0	0	0	1 (1.2)	1
CELLULITIS	1 (1.2)	1	0	0	0	0
CERVICITIS	0	0	0	0	1 (1.2)	2
GASTROENTERITIS VIRAL	0	0	0	0	1 (1.2)	1
HORDEOLUM	0	0	1 (1.2)	1	0	0
LOCALISED INFECTION	0	0	0	0	1 (1.2)	2
LOWER RESPIRATORY TRACT INFECTION	0	0	1 (1.2)	2	0	0
PNEUMONIA	1 (1.2)	2	0	0	0	0
RHINITIS	0	0	1 (1.2)	1	0	0
VAGINAL MYCOSIS	0	0	0	0	1 (1.2)	2

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
VIRAL INFECTION	1 (1.2)	1	0	0	0	0
PSYCHIATRIC DISORDERS	10 (11.9)	14	8 (9.5)	11	10 (11.6)	12
CONFUSIONAL STATE	3 (3.6)	3	1 (1.2)	1	2 (2.3)	2
AGITATION	2 (2.4)	2	1 (1.2)	1	2 (2.3)	2
INSOMNIA	0	0	2 (2.4)	2	2 (2.3)	3
ANXIETY	3 (3.6)	4	0	0	0	0
DELUSION	0	0	1 (1.2)	1	1 (1.2)	1
IRRITABILITY	1 (1.2)	1	0	0	1 (1.2)	2
COMPLETED SUICIDE	0	0	0	0	1 (1.2)	1
DELIRIUM	0	0	1 (1.2)	1	0	0
DEPRESSED MOOD	1 (1.2)	2	0	0	0	0
DISORIENTATION	0	0	0	0	1 (1.2)	1
HALLUCINATION	0	0	1 (1.2)	1	0	0
HALLUCINATION, VISUAL	0	0	1 (1.2)	1	0	0
LIBIDO DECREASED	0	0	1 (1.2)	1	0	0
LISTLESS	0	0	1 (1.2)	1	0	0
NIGHTMARE	0	0	1 (1.2)	1	0	0
RESTLESSNESS	1 (1.2)	2	0	0	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	9 (10.7)	14	10 (11.9)	22	8 (9.3)	12
COUGH	5 (6.0)	7	5 (6.0)	7	1 (1.2)	1
NASAL CONGESTION	1 (1.2)	1	3 (3.6)	4	3 (3.5)	3
DYSPNOEA	1 (1.2)	1	1 (1.2)	1	1 (1.2)	1
EPISTAXIS	1 (1.2)	1	2 (2.4)	2	0	0
PHARYNGOLARYNGEAL PAIN	1 (1.2)	1	1 (1.2)	1	0	0
RHINORRHOEA	1 (1.2)	2	1 (1.2)	2	0	0
ALLERGIC GRANULOMATOUS ANGIITIS	0	0	1 (1.2)	1	0	0

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
DYSPHONIA	1 (1.2)	1	0	0	0	0
EMPHYSEMA	0	0	0	0	1 (1.2)	1
HAEMOPTYSIS	0	0	0	0	1 (1.2)	2
PHARYNGEAL ERYTHEMA	0	0	1 (1.2)	2	0	0
POSTNASAL DRIP	0	0	0	0	1 (1.2)	2
PRODUCTIVE COUGH	0	0	1 (1.2)	1	0	0
RALES	0	0	0	0	1 (1.2)	2
RESPIRATORY TRACT CONGESTION	0	0	1 (1.2)	1	0	0
INVESTIGATIONS	6 (7.1)	7	6 (7.1)	8	10 (11.6)	19
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	1 (1.2)	2	0	0	4 (4.7)	4
ELECTROCARDIOGRAM T WAVE INVERSION	1 (1.2)	1	1 (1.2)	1	2 (2.3)	3
BLOOD GLUCOSE INCREASED	1 (1.2)	1	1 (1.2)	2	0	0
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1 (1.2)	1	0	0	1 (1.2)	1
BIOPSY	0	0	1 (1.2)	1	0	0
BIOPSY PROSTATE	0	0	1 (1.2)	1	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED	0	0	0	0	1 (1.2)	1
BLOOD CHOLESTEROL INCREASED	0	0	1 (1.2)	1	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED	0	0	0	0	1 (1.2)	2
BLOOD URINE PRESENT	0	0	0	0	1 (1.2)	1
BODY TEMPERATURE INCREASED	1 (1.2)	1	0	0	0	0
CYSTOSCOPY	0	0	0	0	1 (1.2)	1
HEART RATE INCREASED	0	0	0	0	1 (1.2)	2
HEART RATE IRREGULAR	0	0	0	0	1 (1.2)	4
NASAL MUCOSA BIOPSY	1 (1.2)	1	0	0	0	0
WEIGHT DECREASED	0	0	1 (1.2)	2	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	7 (8.3)	10	7 (8.3)	10	4 (4.7)	6

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
BACK PAIN	1 (1.2)	1	3 (3.6)	4	1 (1.2)	2
ARTHRALGIA	2 (2.4)	4	1 (1.2)	1	1 (1.2)	1
SHOULDER PAIN	2 (2.4)	2	0	0	1 (1.2)	2
MUSCLE SPASMS	1 (1.2)	1	1 (1.2)	2	0	0
ARTHRITIS	0	0	1 (1.2)	1	0	0
FLANK PAIN	0	0	1 (1.2)	1	0	0
MUSCULAR WEAKNESS	1 (1.2)	2	0	0	0	0
MYALGIA	0	0	1 (1.2)	1	0	0
PAIN IN EXTREMITY	0	0	0	0	1 (1.2)	1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (6.0)	12	5 (6.0)	8	4 (4.7)	9
CONTUSION	1 (1.2)	3	2 (2.4)	3	1 (1.2)	1
EXCORIATION	1 (1.2)	2	1 (1.2)	1	2 (2.3)	3
FALL	2 (2.4)	2	1 (1.2)	1	1 (1.2)	2
HIP FRACTURE	0	0	2 (2.4)	2	1 (1.2)	2
SKIN LACERATION	2 (2.4)	2	0	0	1 (1.2)	1
FACIAL BONES FRACTURE	0	0	1 (1.2)	1	0	0
JOINT DISLOCATION	1 (1.2)	1	0	0	0	0
WOUND	1 (1.2)	2	0	0	0	0
RENAL AND URINARY DISORDERS	3 (3.6)	3	3 (3.6)	4	4 (4.7)	5
MICTURITION URGENCY	1 (1.2)	1	1 (1.2)	2	1 (1.2)	1
DYSURIA	1 (1.2)	1	0	0	1 (1.2)	1
NEPHROLITHIASIS	0	0	1 (1.2)	1	1 (1.2)	1
CALCULUS URETHRAL	0	0	1 (1.2)	1	0	0
INCONTINENCE	1 (1.2)	1	0	0	0	0
POLLAKIURIA	0	0	0	0	1 (1.2)	2

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
METABOLISM AND NUTRITION DISORDERS	1 (1.2)	1	2 (2.4)	4	6 (7.0)	8
DECREASED APPETITE	0	0	1 (1.2)	2	1 (1.2)	2
FOOD CRAVING	1 (1.2)	1	0	0	1 (1.2)	1
INCREASED APPETITE	0	0	1 (1.2)	2	1 (1.2)	2
DEHYDRATION	0	0	0	0	1 (1.2)	1
DIABETES MELLITUS	0	0	0	0	1 (1.2)	1
HYPONATRAEMIA	0	0	0	0	1 (1.2)	1
VASCULAR DISORDERS	3 (3.6)	3	1 (1.2)	1	3 (3.5)	7
HYPOTENSION	1 (1.2)	1	0	0	2 (2.3)	3
HYPERTENSION	1 (1.2)	1	0	0	1 (1.2)	2
HOT FLUSH	1 (1.2)	1	0	0	0	0
ORTHOSTATIC HYPOTENSION	0	0	0	0	1 (1.2)	2
WOUND HAEMORRHAGE	0	0	1 (1.2)	1	0	0
EYE DISORDERS	2 (2.4)	2	1 (1.2)	2	2 (2.3)	5
VISION BLURRED	1 (1.2)	1	1 (1.2)	2	0	0
CONJUNCTIVAL HAEMORRHAGE	1 (1.2)	1	0	0	0	0
CONJUNCTIVITIS	0	0	0	0	1 (1.2)	2
EYE ALLERGY	0	0	0	0	1 (1.2)	1
EYE PRURITUS	0	0	0	0	1 (1.2)	1
EYE SWELLING	0	0	0	0	1 (1.2)	1
SURGICAL AND MEDICAL PROCEDURES	1 (1.2)	1	2 (2.4)	2	2 (2.3)	2
CATARACT OPERATION	1 (1.2)	1	0	0	1 (1.2)	1
ACROCHORDON EXCISION	0	0	1 (1.2)	1	0	0
EYE LASER SURGERY	0	0	0	0	1 (1.2)	1
SKIN LESION EXCISION	0	0	1 (1.2)	1	0	0

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Placebo (N=86)	
System Organ Class/Preferred Term	n %	m	n %	m	n %	m
EAR AND LABYRINTH DISORDERS	2 (2.4)	2	1 (1.2)	1	1 (1.2)	2
VERTIGO	1 (1.2)	1	1 (1.2)	1	0	0
CERUMEN IMPACTION	1 (1.2)	1	0	0	0	0
EAR PAIN	0	0	0	0	1 (1.2)	2
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (1.2)	1	2 (2.4)	2	0	0
VENTRICULAR SEPTAL DEFECT	1 (1.2)	1	2 (2.4)	2	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (2.4)	3	1 (1.2)	1	0	0
COLON CANCER	1 (1.2)	1	0	0	0	0
MALIGNANT FIBROUS HISTIOCYTOMA	1 (1.2)	2	0	0	0	0
PROSTATE CANCER	0	0	1 (1.2)	1	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	0	1 (1.2)	1	2 (2.3)	4
BENIGN PROSTATIC HYPERPLASIA	0	0	1 (1.2)	1	1 (1.2)	2
PELVIC PAIN	0	0	0	0	1 (1.2)	2
HEPATOBILIARY DISORDERS	0	0	0	0	1 (1.2)	1
HYPERBILIRUBINAEMIA	0	0	0	0	1 (1.2)	1
IMMUNE SYSTEM DISORDERS	1 (1.2)	2	0	0	0	0
HYPERSENSITIVITY	1 (1.2)	2	0	0	0	0
SOCIAL CIRCUMSTANCES	0	0	1 (1.2)	1	0	0
ALCOHOL USE	0	0	1 (1.2)	1	0	0

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.

Table 14.3.1.1: Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term
(Safety Analysis Population)

Note: Treatment-Emergent Adverse Events (TEAE) is defined as any adverse events that occurs after the first dose of study treatment.
Note: The MedDRA version is 25.1.
Note: N is the denominator and the number of subjects(n) as numerator, M is the number of events.