Participants with Severe Adverse Events  
(Incidence ≥ 0% in One or More Treatment Groups)  
(ASaT Population)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Placebo | Xanomeline Low Dose | Xanomeline High Dose |
|  | n | n | n |
| Participants in population | 86 | 84 | 84 |
| with one or more severe AE | 7 | 16 | 8 |
| with no severe AE | 79 | 68 | 76 |
|  |  |  |  |
| cardiac disorders | 3 | 0 | 1 |
| atrial fibrillation | 0 | 0 | 1 |
| atrioventricular block second degree | 1 | 0 | 0 |
| myocardial infarction | 2 | 0 | 0 |
| gastrointestinal disorders | 0 | 0 | 2 |
| gastrointestinal haemorrhage | 0 | 0 | 1 |
| nausea | 0 | 0 | 1 |
| general disorders and administration site conditions | 0 | 7 | 0 |
| application site dermatitis | 0 | 1 | 0 |
| application site erythema | 0 | 2 | 0 |
| application site irritation | 0 | 3 | 0 |
| application site pruritus | 0 | 1 | 0 |
| application site warmth | 0 | 1 | 0 |

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(ASaT Population)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Placebo | Xanomeline Low Dose | Xanomeline High Dose |
|  | n | n | n |
| general disorders and administration site conditions | 0 | 7 | 0 |
| sudden death | 0 | 1 | 0 |
| infections and infestations | 0 | 1 | 0 |
| nasopharyngitis | 0 | 1 | 0 |
| injury, poisoning and procedural complications | 1 | 0 | 1 |
| hip fracture | 1 | 0 | 1 |
| musculoskeletal and connective tissue disorders | 1 | 1 | 0 |
| arthritis | 1 | 0 | 0 |
| muscle spasms | 0 | 1 | 0 |
| neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 1 | 1 |
| colon cancer | 0 | 1 | 0 |
| prostate cancer | 0 | 0 | 1 |
| nervous system disorders | 0 | 3 | 4 |
| dizziness | 0 | 0 | 1 |
| headache | 0 | 1 | 0 |
| partial seizures with secondary generalisation | 0 | 0 | 1 |
| stupor | 0 | 1 | 0 |
| syncope | 0 | 2 | 1 |
| transient ischaemic attack | 0 | 1 | 1 |

Participants with Severe Adverse Events  
(Incidence ≥ 0% in One or More Treatment Groups)  
(ASaT Population)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Placebo | Xanomeline Low Dose | Xanomeline High Dose |
|  | n | n | n |
| psychiatric disorders | 1 | 1 | 0 |
| agitation | 0 | 1 | 0 |
| completed suicide | 1 | 0 | 0 |
| reproductive system and breast disorders | 1 | 0 | 0 |
| benign prostatic hyperplasia | 1 | 0 | 0 |
| skin and subcutaneous tissue disorders | 0 | 4 | 1 |
| blister | 0 | 1 | 0 |
| pruritus | 0 | 1 | 0 |
| rash | 0 | 1 | 1 |
| skin irritation | 0 | 1 | 0 |
| This is footnote | | | |

Source:    [Study MK9999P001: adam-adae]