Listing of Subjects With Serious Adverse Events  
ASaT

**Trial Number: CDISCPILOT01, Site Number: 701**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject | Rel Day | Adverse |  |  |  |  | Action |  |
| ID | of Onset | Event | Duration | Intensity | Serious | Related | Taken | Outcome |
| **Placebo** | | | | | | | | |
| Subject ID = 01-701-1363, Gender = F, Race = BLACK OR AFRICAN AMERICAN, AGE = 81 Years, TRT = Placebo | | | | | | | | |
| 01-701-1363 | 16 | NAUSEA | 2 DAY | MILD | N | REMOTE |  | RECOVERED/RESOLVED |
|  | 48 | APPLICATION SITE PRURITUS | NA | MILD | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  | 137 | BACK PAIN | 3 DAY | MILD | N | NONE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | BACK PAIN | 3 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |
|  |  | HEADACHE | NA | MODERATE | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | HEADACHE | NA | MILD | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |
| Subject ID = 01-701-1387, Gender = F, Race = WHITE, AGE = 87 Years, TRT = Placebo | | | | | | | | |
| 01-701-1387 | 7 | DIARRHOEA | 1 DAY | MILD | N | REMOTE |  | RECOVERED/RESOLVED |
|  |  | HYPERHIDROSIS | 1 DAY | MILD | N | REMOTE |  | RECOVERED/RESOLVED |

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**Trial Number: CDISCPILOT01, Site Number: 701**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject | Rel Day | Adverse |  |  |  |  | Action |  |
| ID | of Onset | Event | Duration | Intensity | Serious | Related | Taken | Outcome |
| **Placebo** | | | | | | | | |
| Subject ID = 01-701-1392, Gender = M, Race = WHITE, AGE = 78 Years, TRT = Placebo | | | | | | | | |
| 01-701-1392 | 140 | UPPER RESPIRATORY TRACT INFECTION | 6 DAY | MILD | N | REMOTE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | UPPER RESPIRATORY TRACT INFECTION | 6 DAY | MILD | N | REMOTE |  | RECOVERED/RESOLVED |
| Subject ID = 01-701-1415, Gender = M, Race = WHITE, AGE = 85 Years, TRT = Placebo | | | | | | | | |
| 01-701-1415 | 29 | UPPER RESPIRATORY TRACT INFECTION | 15 DAY | MILD | N | NONE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | UPPER RESPIRATORY TRACT INFECTION | 15 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |
|  | 71 | MICTURITION URGENCY | NA | MILD | N | NONE |  | NOT RECOVERED/NOT RESOLVED |
|  | 121 | UPPER RESPIRATORY TRACT INFECTION | 21 DAY | MILD | N | REMOTE |  | NOT RECOVERED/NOT RESOLVED |

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**Trial Number: CDISCPILOT01, Site Number: 701**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject | Rel Day | Adverse |  |  |  |  | Action |  |
| ID | of Onset | Event | Duration | Intensity | Serious | Related | Taken | Outcome |
| **Placebo** | | | | | | | | |
| Subject ID = 01-701-1415, Gender = M, Race = WHITE, AGE = 85 Years, TRT = Placebo | | | | | | | | |
| 01-701-1415 | 121 | UPPER RESPIRATORY TRACT INFECTION | 21 DAY | MILD | N | REMOTE |  | RECOVERED/RESOLVED |
|  | 168 | DIARRHOEA | 1 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |
| **Xanomeline High Dose** | | | | | | | | |
| Subject ID = 01-701-1360, Gender = M, Race = WHITE, AGE = 67 Years, TRT = Xanomeline High Dose | | | | | | | | |
| 01-701-1360 | 3 | APPLICATION SITE PRURITUS | NA | MODERATE | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  | 6 | APPLICATION SITE VESICLES | NA | MODERATE | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
| Subject ID = 01-701-1383, Gender = F, Race = WHITE, AGE = 72 Years, TRT = Xanomeline High Dose | | | | | | | | |
| 01-701-1383 | 4 | APPLICATION SITE PRURITUS | 1 DAY | MILD | N | PROBABLE |  | RECOVERED/RESOLVED |
|  |  | APPLICATION SITE PAIN | 1 DAY | MILD | N | PROBABLE |  | RECOVERED/RESOLVED |
|  | 48 | APPLICATION SITE ERYTHEMA | 4 DAY | MILD | N | POSSIBLE |  | RECOVERED/RESOLVED |
|  |  | APPLICATION SITE PRURITUS | NA | MILD | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |

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**Trial Number: CDISCPILOT01, Site Number: 701**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject | Rel Day | Adverse |  |  |  |  | Action |  |
| ID | of Onset | Event | Duration | Intensity | Serious | Related | Taken | Outcome |
| **Xanomeline High Dose** | | | | | | | | |
| Subject ID = 01-701-1383, Gender = F, Race = WHITE, AGE = 72 Years, TRT = Xanomeline High Dose | | | | | | | | |
| 01-701-1383 | 48 | APPLICATION SITE PRURITUS | NA | MODERATE | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |
|  | 68 | APPLICATION SITE ERYTHEMA | NA | MILD | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | APPLICATION SITE IRRITATION | NA | MILD | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | APPLICATION SITE IRRITATION | NA | MODERATE | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |
|  | 93 | APPLICATION SITE VESICLES | 18 DAY | MILD | N | POSSIBLE |  | RECOVERED/RESOLVED |
|  | 141 | CHEST DISCOMFORT | 1 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |
|  |  | HEADACHE | 1 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |
|  | 164 | COUGH | 10 DAY | MODERATE | N | NONE |  | RECOVERED/RESOLVED |
| Subject ID = 01-701-1444, Gender = M, Race = WHITE, AGE = 63 Years, TRT = Xanomeline High Dose | | | | | | | | |
| 01-701-1444 | 15 | APPLICATION SITE ERYTHEMA | NA | MILD | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |

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**Trial Number: CDISCPILOT01, Site Number: 701**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject | Rel Day | Adverse |  |  |  |  | Action |  |
| ID | of Onset | Event | Duration | Intensity | Serious | Related | Taken | Outcome |
| **Xanomeline High Dose** | | | | | | | | |
| Subject ID = 01-701-1444, Gender = M, Race = WHITE, AGE = 63 Years, TRT = Xanomeline High Dose | | | | | | | | |
| 01-701-1444 | 15 | APPLICATION SITE PRURITUS | NA | MILD | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | SALIVARY HYPERSECRETION | NA | MILD | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | APPLICATION SITE ERYTHEMA | NA | MODERATE | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | APPLICATION SITE PRURITUS | NA | MODERATE | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  | 31 | APPLICATION SITE IRRITATION | NA | MODERATE | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | APPLICATION SITE VESICLES | NA | MODERATE | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  | 35 | PARAESTHESIA | 1 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |
| **Xanomeline Low Dose** | | | | | | | | |
| Subject ID = 01-701-1442, Gender = F, Race = BLACK OR AFRICAN AMERICAN, AGE = 57 Years, TRT = Xanomeline Low Dose | | | | | | | | |
| 01-701-1442 | 77 | APPLICATION SITE PRURITUS | NA | MILD | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |

Listing of Subjects With Serious Adverse Events  
ASaT

**Trial Number: CDISCPILOT01, Site Number: 702**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject | Rel Day | Adverse |  |  |  |  | Action |  |
| ID | of Onset | Event | Duration | Intensity | Serious | Related | Taken | Outcome |
| **Xanomeline Low Dose** | | | | | | | | |
| Subject ID = 01-702-1082, Gender = F, Race = WHITE, AGE = 84 Years, TRT = Xanomeline Low Dose | | | | | | | | |
| 01-702-1082 | -19 | WHITE BLOOD CELL COUNT INCREASED | 20 DAY | MILD | N | NONE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | NEUTROPHIL COUNT INCREASED | 20 DAY | MILD | N | NONE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | URINE ANALYSIS ABNORMAL | 18 DAY | MILD | N | NONE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | URINE ANALYSIS ABNORMAL | 18 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |
|  |  | WHITE BLOOD CELL COUNT INCREASED | 20 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |

Listing of Subjects With Serious Adverse Events  
ASaT

**Trial Number: CDISCPILOT01, Site Number: 702**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject | Rel Day | Adverse |  |  |  |  | Action |  |
| ID | of Onset | Event | Duration | Intensity | Serious | Related | Taken | Outcome |
| **Xanomeline Low Dose** | | | | | | | | |
| Subject ID = 01-702-1082, Gender = F, Race = WHITE, AGE = 84 Years, TRT = Xanomeline Low Dose | | | | | | | | |
| 01-702-1082 | -19 | NEUTROPHIL COUNT INCREASED | 20 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |
|  | 39 | RECTAL HAEMORRHAGE | 5 DAY | MILD | N | NONE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | RECTAL HAEMORRHAGE | 5 DAY | MILD | N | NONE |  | RECOVERED/RESOLVED |
|  | 46 | APPLICATION SITE IRRITATION | 16 DAY | MILD | N | PROBABLE |  | RECOVERED/RESOLVED |
|  | 79 | SKIN IRRITATION | 20 DAY | MODERATE | N | PROBABLE |  | RECOVERED/RESOLVED |

Listing of Subjects With Serious Adverse Events  
ASaT

**Trial Number: CDISCPILOT01, Site Number: 703**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject | Rel Day | Adverse |  |  |  |  | Action |  |
| ID | of Onset | Event | Duration | Intensity | Serious | Related | Taken | Outcome |
| **Placebo** | | | | | | | | |
| Subject ID = 01-703-1042, Gender = M, Race = WHITE, AGE = 64 Years, TRT = Placebo | | | | | | | | |
| 01-703-1042 | 3 | DIARRHOEA | 2 DAY | MILD | N | POSSIBLE |  | RECOVERED/RESOLVED |
|  | 4 | INSOMNIA | 2 DAY | MILD | N | REMOTE |  | RECOVERED/RESOLVED |
| **Xanomeline High Dose** | | | | | | | | |
| Subject ID = 01-703-1076, Gender = M, Race = WHITE, AGE = 69 Years, TRT = Xanomeline High Dose | | | | | | | | |
| 01-703-1076 | 23 | BIOPSY PROSTATE | 1 DAY | MODERATE | N | NONE |  | RECOVERED/RESOLVED |
|  | 27 | BENIGN PROSTATIC HYPERPLASIA | NA | MODERATE | N | NONE |  | NOT RECOVERED/NOT RESOLVED |
|  | 30 | APPLICATION SITE PRURITUS | NA | MILD | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | APPLICATION SITE DERMATITIS | NA | MILD | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | APPLICATION SITE PRURITUS | NA | MODERATE | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |

Listing of Subjects With Serious Adverse Events  
ASaT

**Trial Number: CDISCPILOT01, Site Number: 703**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject | Rel Day | Adverse |  |  |  |  | Action |  |
| ID | of Onset | Event | Duration | Intensity | Serious | Related | Taken | Outcome |
| **Xanomeline High Dose** | | | | | | | | |
| Subject ID = 01-703-1076, Gender = M, Race = WHITE, AGE = 69 Years, TRT = Xanomeline High Dose | | | | | | | | |
| 01-703-1076 | 32 | HYPERHIDROSIS | NA | MILD | N | POSSIBLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | HYPERCHOLESTEROLAEMIA | NA | MODERATE | N | NONE |  | NOT RECOVERED/NOT RESOLVED |
| **Xanomeline Low Dose** | | | | | | | | |
| Subject ID = 01-703-1086, Gender = M, Race = WHITE, AGE = 71 Years, TRT = Xanomeline Low Dose | | | | | | | | |
| 01-703-1086 | 12 | APPLICATION SITE IRRITATION | 112 DAY | MILD | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | APPLICATION SITE IRRITATION | 112 DAY | MODERATE | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
|  |  | APPLICATION SITE IRRITATION | 112 DAY | SEVERE | N | PROBABLE |  | NOT RECOVERED/NOT RESOLVED |
| This is footnote 1 | | | | | | | | |

Source:    [Study MK9999P001: adam-adae]