

Listing of Subjects With Serious Adverse Events  
ASaT

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

| Subject ID  | Rel Day of Onset | Adverse Event             | Duration | Intensity | Serious | Related  | Action Taken | Outcome                    |
|---|------------------|---------------------------|----------|-----------|---------|----------|--------------|----------------------------|
| <b>Placebo</b>  |                  |                           |          |           |         |          |              |                            |
| 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         |
|   |                  | HYPERTHYROIDISM           | 1 DAY    | MILD      | N       | REMOTE   |              | RECOVERED/RESOLVED         |

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| <b>Placebo</b>  |                  |  |                |              |         |                  |              |  |
| Subject ID = 01-701-1392, Gender = M, Race = WHITE, AGE = 78 Years, TRT = Placebo |                  |  |                |              |         |                  |              |  |
| 01-701-1392   | 140              | UPPER RESPIRATORY TRACT INFECTION<br>UPPER RESPIRATORY TRACT INFECTION | 6 DAY<br>6 DAY | MILD<br>MILD | N<br>N  | REMOTE<br>REMOTE |              | NOT RECOVERED/NOT RESOLVED<br>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                       |
|   | 71               | UPPER RESPIRATORY TRACT INFECTION<br>MICTURITION URGENCY               | 15 DAY<br>NA   | MILD<br>MILD | N<br>N  | NONE<br>NONE     |              | RECOVERED/RESOLVED<br>NOT RECOVERED/NOT RESOLVED |
|   | 121              | UPPER RESPIRATORY TRACT INFECTION                                      | 21 DAY         | MILD         | N       | REMOTE           |              | NOT RECOVERED/NOT RESOLVED                       |

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| <b>Placebo</b>   |                  |                                   |          |           |         |          |              |                            |
| 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         |
| <b>Xanomeline High Dose</b>  |                  |                                   |          |           |         |          |              |                            |
| 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         |
|  | 48               | APPLICATION SITE PAIN             | 1 DAY    | MILD      | N       | PROBABLE |              | RECOVERED/RESOLVED         |
|  |                  | 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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|--|------------------|-----------------------------|----------|-----------|---------|----------|--------------|----------------------------|
| <b>Xanomeline High Dose</b>  |                  |                             |          |           |         |          |              |                            |
| 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 |
|  |                  | APPLICATION SITE PRURITUS   | NA       | MILD      | N       | PROBABLE |              | NOT RECOVERED/NOT RESOLVED |

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|---|------------------|-----------------------------|----------|-----------|---------|----------|--------------|----------------------------|
| <b>Xanomeline High Dose</b>   |                  |                             |          |           |         |          |              |                            |
| Subject ID = 01-701-1444, Gender = M, Race = WHITE, AGE = 63 Years, TRT = Xanomeline High Dose                    |                  |                             |          |           |         |          |              |                            |
| 01-701-1444   | 15               | SALIVARY HYPERSECRETION     | NA       | MILD      | N       | POSSIBLE |              | NOT RECOVERED/NOT RESOLVED |
|   |                  | APPLICATION SITE ERYTHEMA   | NA       | MODERATE  | N       | POSSIBLE |              | NOT RECOVERED/NOT RESOLVED |
|   | 31               | APPLICATION SITE PRURITUS   | NA       | MODERATE  | N       | PROBABLE |              | NOT RECOVERED/NOT RESOLVED |
|   |                  | 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         |
| <b>Xanomeline Low Dose</b>  |                  |                             |          |           |         |          |              |                            |
| 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 |

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| Subject ID  | Rel Day of Onset | Adverse Event                    | Duration | Intensity | Serious | Related | Action Taken | Outcome                    |
|---|------------------|----------------------------------|----------|-----------|---------|---------|--------------|----------------------------|
| <b>Xanomeline Low Dose</b>  |                  |                                  |          |           |         |         |              |                            |
| 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         |
|   |                  | NEUTROPHIL COUNT INCREASED       | 20 DAY   | MILD      | N       | NONE    |              | RECOVERED/RESOLVED         |

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|---|------------------|-----------------------------|----------|-----------|---------|----------|--------------|----------------------------|
| <b>Xanomeline Low Dose</b>  |                  |                             |          |           |         |          |              |                            |
| Subject ID = 01-702-1082, Gender = F, Race = WHITE, AGE = 84 Years, TRT = Xanomeline Low Dose |                  |                             |          |           |         |          |              |                            |
| 01-702-1082   | 39               | RECTAL HAEMORRHAGE          | 5 DAY    | MILD      | N       | NONE     |              | NOT RECOVERED/NOT RESOLVED |
|   | 46               | RECTAL HAEMORRHAGE          | 5 DAY    | MILD      | N       | NONE     |              | RECOVERED/RESOLVED         |
|   | 79               | APPLICATION SITE IRRITATION | 16 DAY   | MILD      | N       | PROBABLE |              | RECOVERED/RESOLVED         |
|   |                  | SKIN IRRITATION             | 20 DAY   | MODERATE  | N       | PROBABLE |              | RECOVERED/RESOLVED         |

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

| Subject ID   | Rel Day of Onset     | Adverse Event   | Duration                            | Intensity  | Serious                    | Related  | Action Taken | Outcome  |
|--|----------------------|---|-------------------------------------|--|----------------------------|--|--------------|--|
| <b>Placebo</b>   |                      |   |                                     |  |                            |  |              |  |
| Subject ID = 01-703-1042, Gender = M, Race = WHITE, AGE = 64 Years, TRT = Placebo              |                      |   |                                     |  |                            |  |              |  |
| 01-703-1042  | 3<br>4               | DIARRHOEA<br>INSOMNIA   | 2 DAY<br>2 DAY                      | MILD<br>MILD   | N<br>N                     | POSSIBLE<br>REMOTE   |              | RECOVERED/RESOLVED<br>RECOVERED/RESOLVED   |
| <b>Xanomeline High Dose</b>  |                      |   |                                     |  |                            |  |              |  |
| Subject ID = 01-703-1076, Gender = M, Race = WHITE, AGE = 69 Years, TRT = Xanomeline High Dose |                      |   |                                     |  |                            |  |              |  |
| 01-703-1076  | 23<br>27<br>30<br>32 | BIOPSY PROSTATE<br>BENIGN PROSTATIC HYPERPLASIA<br>APPLICATION SITE PRURITUS<br>APPLICATION SITE DERMATITIS<br>APPLICATION SITE PRURITUS<br>HYPERHIDROSIS | 1 DAY<br>NA<br>NA<br>NA<br>NA<br>NA | MODERATE<br>MODERATE<br>MILD<br>MILD<br>MODERATE<br>MILD | N<br>N<br>N<br>N<br>N<br>N | NONE<br>NONE<br>PROBABLE<br>PROBABLE<br>PROBABLE<br>POSSIBLE |              | RECOVERED/RESOLVED<br>NOT RECOVERED/NOT RESOLVED<br>NOT RECOVERED/NOT RESOLVED<br>NOT RECOVERED/NOT RESOLVED<br>NOT RECOVERED/NOT RESOLVED<br>NOT RECOVERED/NOT RESOLVED |

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ASaT

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

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

Source: [Study CDISCPILOT01: adam-adae]

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