

**FDA-AE-T06****Overview of Adverse Events****Safety Population**

<b>Event</b>	<b>Xanomeline Low Dose (N=XX) n (%)</b>	<b>Xanomeline High Dose (N=XX) n (%)</b>	<b>Placebo (N=XX) n (%)</b>	<b>Risk Difference (%) (95% CI) [1]</b>	<b>Risk Difference (%) (95% CI) [2]</b>
<b>SAE [3]</b>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Results in Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Is Life Threatening	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Requires or Prolongs Hospitalization	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Persist or Significant Disability / Incapacity	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Congenital Anomaly or Birth Defect	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Other [4]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
<b>AE leading to permanent discontinuation of study drug</b>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)

<b>AE leading to dose modification of study drug</b>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
AE leading to interruption of study drug	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
AE leading to reduction of study drug	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
AE leading to dose delay of study drug	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
<b>Any AE [5]</b>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)

Source: ADAE; Program name: fda-ae-t06.sas;

Abbreviations: AE, adverse event; CI, confidence interval; N, number of subjects in treatment arm; n, number of subjects with at least one event; SAE, serious adverse event

[1] Difference is shown between Xanomeline Low Dose vs. Placebo.

[2] Difference is shown between Xanomeline High Dose vs. Placebo.

[3] SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent incapacity or substantial disruption of the ability to conduct normal life functions, is a congenital anomaly or birth defect, or involves overdose, cancer, or additional uncategorized adverse events.

[4] Other includes serious adverse events that involve overdose, cancer, or additional uncategorized adverse events.

[5] Severity as assessed by the investigator.