

FDA-AE-T12

Subjects With Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term

Safety Population

System Organ Class Preferred Term [1]	Xanomeline Low Dose (N=XX) n (%)	Xanomeline High Dose (N=XX) n (%)	Placebo (N=XX) n (%)	Risk Difference (%) (95% CI) [2]	Risk Difference (%) (95% CI) [3]
Subjects with at least one TEAE leading to discontinuation [4]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
SOC {alphabetical order}	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
PT {alphabetical order}	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-t12.sas;

Abbreviations: CI, confidence interval; MedDRA, Medical Dictionary for Regulatory Activities; N, number of subjects in treatment arm; n, number of subjects with at least one event; TEAE, Treatment-Emergent Adverse Events; SOC, System Organ Class; PT, Preferred Term.

Note: Subjects are counted once within each system organ class and preferred term.

[1] All adverse events were coded using MedDRA version xx.x.

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

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

[4] Treatment-emergent adverse event is defined as AE with onset after the first dose of study drug.