

Table 14-3.01
Primary Endpoint Analysis: ADAS Cog (11) - Change from Baseline to Week 24 - LOCF

	Placebo (N=79)	Xanomeline Low Dose (N=81)	Xanomeline High Dose (N=74)
Baseline			
n	79	81	74
Mean (SD)	24.1 (12.19)	24.4 (12.92)	21.3 (11.74)
Median (Range)	21.0 (5;61)	21.0 (5;57)	18.0 (3;57)
Week 24			
n	79	81	74
Mean (SD)	26.8 (13.78)	26.5 (13.30)	22.7 (12.54)
Median (Range)	24.0 (5;62)	25.0 (6;62)	20.0 (3;62)
Change from Baseline			
n	79	81	74
Mean (SD)	2.6 (5.83)	2.0 (5.62)	1.4 (4.40)
Median (Range)	2.0 (-11;16)	2.0 (-11;17)	1.0 (-7;14)
p-value(Dose Response) [1][2]			0.187
p-value(Xan - Placebo) [1][3]		0.534	0.173
Diff of LS Means (SE)		-0.5 (0.83)	-1.2 (0.86)
95% CI		(-2.2;1.1)	(-2.9;0.5)
p-value(Xan High - Xan Low) [1][3]			0.446
Diff of LS Means (SE)			-0.6 (0.85)
95% CI			(-2.3;1.0)

[1] Based on Analysis of covariance (ANCOVA) model with treatment and site group as factors and baseline value as a covariate.

[2] Test for a non-zero coefficient for treatment (dose) as a continuous variable

[3] Pairwise comparison with treatment as a categorical variable: p-values without adjustment for multiple comparisons.

Source: <run interactively>18:25 Friday, August 25, 2023