

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

	Placebo (N=79)	Xanomeline High Dose (N=74)	Xanomeline Low Dose (N=81)
Baseline			
n	79	74	81
Mean (SD)	24.1 (12.19)	21.3 (11.74)	24.4 (12.92)
Median (Range)	21.0 (5;61)	18.0 (3;57)	21.0 (5;57)
Week 24			
n	79	74	81
Mean (SD)	26.7 (13.79)	22.8 (12.48)	26.4 (13.18)
Median (Range)	24.0 (5;62)	20.0 (3;62)	25.0 (6;62)
Change from Baseline			
n	79	74	81
Mean (SD)	2.5 (5.80)	1.5 (4.26)	2.0 (5.55)
Median (Range)	2.0 (-11;16)	1.0 (-7;13)	2.0 (-11;17)
p-value(Dose Response) [1][2]		0.245	
p-value(Xan - Placebo) [1][3]		0.233	0.569
Diff of LS Means (SE)		-1.0 (0.84)	-0.5 (0.82)
95% CI		(-2.7;0.7)	(-2.1;1.1)
p-value(Xan High - Xan Low) [1][3]		0.520	
Diff of LS Means (SE)		-0.5 (0.84)	
95% CI		(-2.2;1.1)	

[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.