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Population: Efficacy

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