Population: Efficacy

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

	Placebo (N=79)	Xanomeline Log Dose (N=81)	wXanomeline High Dose (N=74)
Baseline			
n	79	74	81
Mean (SD)	24.1 (12.19)	21.3 (11.74)	24.4 (12.92)
Median (Range) Week 24	21.0 ( 5;61)	18.0 ( 3;57)	21.0 ( 5;57)
n	79	74	81
Mean (SD)	26.7 (13.79)	22.8 (12.48)	26.4 (13.18)
Median (Range)	24.0 ( 5;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] Diff of LS Means (SE)		0.520 -0.5 (0.84)	
95% CI		(-2.2;1.1)	

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

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

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