

Table 14-3.09
ADAS Cog (11) - Change from Baseline to Week 24 in Female Subjects - LOCF

	Placebo (N=46)	Xanomeline Low Dose (N=47)	Xanomeline High Dose (N=35)
Baseline			
n	46	47	35
Mean (SD)	25.1 (11.25)	25.2 (12.15)	21.8 (12.54)
Median (Range)	23.5 (5;51)	21.0 (5;55)	18.0 (5;57)
Week 24			
n	46	47	35
Mean (SD)	28.1 (13.70)	26.9 (12.09)	22.9 (12.84)
Median (Range)	24.0 (8;59)	25.0 (8;62)	19.0 (4;62)
Change from Baseline			
n	46	47	35
Mean (SD)	3.0 (5.57)	1.7 (5.54)	1.1 (4.77)
Median (Range)	3.0 (-8;16)	2.0 (-11;17)	0.0 (-7;13)
p-value(Dose Response) [1][2]			0.094
p-value(Xan - Placebo) [1][3]		0.160	0.135
Diff of LS Means (SE)		-1.6 (1.10)	-1.8 (1.20)
95% CI		(-3.7;0.6)	(-4.2;0.6)
p-value(Xan High - Xan Low) [1][3]			0.843
Diff of LS Means (SE)			-0.2 (1.21)
95% CI			(-2.6;2.2)

[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: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rtf_eff1.sas

21:05 Monday, June 26, 2006