Table 1: Table 14-3.05

ADAS Cog (11) - Change from Baseline to Week 16 - LOCF

|  |  | Xanomeline (N=155) | |
| --- | --- | --- | --- |
| Placebo (N=79) | Low Dose (N=81) | 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 16 |  |  |  |
| n | 71 | 47 | 42 |
| Mean (SD) | 25.2 (13.31) | 26.2 (11.52) | 21.8 (12.30) |
| Median (Range) | 21.0 ( 5;63) | 25.0 ( 8;53) | 18.5 ( 4;49) |
| Change from Baseline |  |  |  |
| n | 71 | 47 | 42 |
| Mean (SD) | 1.9 ( 5.85) | 1.6 ( 5.10) | 1.3 ( 4.58) |
| Median (Range) | 2.0 (-17;23) | 1.0 (-8;13) | 2.0 (-11;10) |
|  |  |  |  |
| p-value (Dose Response)*1,2* |  |  | 0.412 |
|  |  |  |  |
| p-value (Xanomeline - Placebo)*1,3* |  | 0.724 | 0.392 |
| Diff of LS Means (SE) |  | -0.3 ( 0.77) | -0.7 ( 0.79) |
| 95% CI |  | (-1.8; 1.2) | (-2.2; 0.9) |
|  |  |  |  |
| p-value (Xanomeline High - Xanomeline Low)*1,3* |  |  | 0.606 |
| Diff of LS Means (SE) |  |  | -0.4 ( 0.78) |
| 95% CI |  |  | (-1.9; 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. | | | |