| **TEFMAD01A: Montgomery-Asberg Depression Rating Scale (MADRS) Total Score: Change from Baseline to Day 28 MMRM; Double-blind Treatment Phase (Dummy Study: Full Analysis Set)** | | |
| --- | --- | --- |
|  | Dummy A (N=119) | Dummy B (N=118) |
|  |  |  |
| Baseline |  |  |
| N | 119 | 118 |
| Mean (SD) | 36.5 (4.58) | 35.9 (5.06) |
| Median (Range) | 36.0 (27; 48) | 36.0 (25; 50) |
|  |  |  |
| Day 28 |  |  |
| N | 105 | 98 |
| Mean (SD) | 26.7 (10.35) | 27.1 (10.42) |
| Median (Range) | 29.0 (0; 43) | 29.0 (0; 44) |
|  |  |  |
| Change from baseline to day 28 |  |  |
| N | 105 | 98 |
| Mean (SD) | -9.7 (11.07) | -8.9 (10.22) |
| Median (Range) | -7.0 (-42; 8) | -6.0 (-36; 8) |
|  |  |  |
| MMRM analysis (a) |  |  |
| Diff. of LS means (SE) (A minus B) | -0.6 (1.38) |  |
| 95% confidence interval on diff. | -3.29; 2.13 |  |
| 2-sided p-value | 0.674 |  |
| (a) Test for treatment effect is based on mixed model for repeated measures (MMRM) with change from baseline as the response variable and the fixed effect model terms for treatment, day, country and treatment-by-day, and baseline value as a covariate.  Note: MADRS total score ranges from 0 to 60; a higher score indicates a more severe condition. Note: Negative change in score indicates improvement. | | |
| [TEFMAD01A.RTF] [Dummy compound\study ID\DBR\_FINAL\RE\_CSR\PREPROD\TEFMAD01A.SAS] 20JAN2021, 02:31 | | |