Table e-3: Sleep parameters in male and female subjects

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mean (SD) | Placebo  (N=54) | | Daridorexant | | | | | | | |
| 5 mg  (N=56) | | 10 mg  (N=54) | | 25 mg  (N=55) | | 50 mg  (N=56) | |
| Male  (n=18) | Female  (n=36) | Male  (n=19) | Female  (n=37) | Male  (n=18) | Female  (n=36) | Male  (n=19) | Female  (n=36) | Male  (n=18) | Female  (n=38) |
| **Primary endpoint** |  |  |  |  |  |  |  |  |  |  |
| WASO, min |  |  |  |  |  |  |  |  |  |  |
| Baseline | 129.5  (35.9) | 111.7  (40.6) | 124.5  (41.2) | 112.7  (40.4) | 129.5  (35.9) | 111.7  (40.6) | 124.5  (41.2) | 111.7  (40.6) | 129.5  (35.9) | 110.0  (40.6) |
| Change at Days 1&2 | –12.6  (42.7) | –14.9  (48.5) | –20.7  (39.6) | –17.3  (54.7) | –28.7  (29.6) | –34.2  (42.5) | –41.8  (46.5) | –45.5  (45.2) | –65.9  (30.4) | –58.8  (46.9) |
| **Secondary endpoint** |  |  |  |  |  |  |  |  |  |  |
| LPS |  |  |  |  |  |  |  |  |  |  |
| Baseline | 76.1  (59.6) | 73.4  (43.7) | 83.1  (65.3) | 72.3  (43.6) | 76.1  (59.6) | 73.4  (43.7) | 83.1  (65.3) | 73.4  (43.7) | 76.1  (59.6) | 73.1  (43.0) |
| Change at Days 1&2 | –32.6  (48.8) | –34.5  (38.5) | –52.8  (59.4) | –30.3  (41.1) | –44.5  (52.0) | –44.7  (35.6) | –42.9  (52.3) | –45.8  (35.5) | –47.8  (57.2) | –43.5  (37.4) |
| **Other efficacy endpoints** |  |  |  |  |  |  |  |  |  |  |
| sWASO |  |  |  |  |  |  |  |  |  |  |
| Baseline | 107.4  (48.5) | 94.7  (73.5) | 110.4  (49.0) | 95.7  (72.8) | 107.4  (48.5) | 94.7  (73.5) | 110.4  (49.0) | 94.7  (73.5) | 107.4  (48.5) | 95.2  (71.6) |
| Change at Days 1&2 | –14.4  (48.6) | –9.1  (79.0) | –31.0  (52.2) | –12.4  (77.6) | –32.4  (44.4) | –21.6  (70.2) | –41.0  (53.8) | –37.0  (67.8) | –41.8  (45.6) | –35.8  (77.7) |
| sLSO |  |  |  |  |  |  |  |  |  |  |
| Baseline | 66.9  (43.7) | 64.4  (43.5) | 70.5  (45.2) | 63.8  (43.1) | 66.9  (43.7) | 64.4  (43.5) | 70.5  (45.2) | 64.4  (43.5) | 66.9  (43.7) | 64.8  (42.6) |
| Change at Days 1&2 | –19.4  (33.8) | –11.2  (41.8) | –27.2  (33.4) | –8.5  (26.1) | –22.6  (32.5) | –23.9  (32.1) | –25.8  (28.8) | –21.6  (34.1) | –33.5  (24.0) | –23.8  (39.3) |
| TST, min |  |  |  |  |  |  |  |  |  |  |
| Baseline | 282.9  (49.9) | 302.2  (60.8) | 281.0  (49.1) | 302.3  (59.9) | 282.9  (49.9) | 302.2  (60.8) | 281.0  (49.1) | 302.2  (60.8) | 282.9  (49.9) | 304.5  (61.3) |
| Change at Days 1&2 | 44.4  (38.6) | 44.8  (51.5) | 70.6  (46.9) | 45.3  (59.9) | 69.7  (37.5) | 76.2  (54.4) | 85.8  (39.8) | 88.5  (51.9) | 115.4  (41.5) | 100.0  (56.3) |
| sTST, min |  |  |  |  |  |  |  |  |  |  |
| Baseline | 304.3  (57.7) | 300.5  (69.2) | 304.9  (56.1) | 299.7  (68.4) | 304.3  (57.7) | 300.5  (69.2) | 304.9  (56.1) | 300.5  (69.2) | 304.3  (57.7) | 300.3  (67.3) |
| Change at Days 1&2 | 28.8  (50.5) | 34.8  (78.2) | 28.8  (59.0) | 26.1  (71.8) | 28.6  (58.6) | 57.1  (68.8) | 47.3  (50.0) | 60.8  (61.9) | 72.5  (44.7) | 68.1  (79.1) |

Days 1&2 refers to the mean value of the corresponding two PSG treatment nights for a given treatment period.

LPS, latency to persistent sleep; SD, standard deviation; sLSO, subjective latency to sleep onset; sTST, self-reported total sleep time; sWASO, subjective wake after sleep onset; TST, total sleep time; WASO, wake after sleep onset.