**Supplemental Table 1. Double-Blind PP1M versus Placebo Treatment Phase: TEAEs, Weight and Prolactin-Related Measures**

|  | **Recent Onset** | **Chronic Illness** |
| --- | --- | --- |
| Paliperidone Monthly (n=59) | Placebo (n=60) | Paliperidone Monthly (n=105) | Placebo (n=110) |
| Any TEAE | 36 (61.0%) | 32 (53.3%) | 70 (66.7%) | 63 (57.3%) |
| **Discontinuation due to TEAE** | 4 (6.8%) | 0 (0) | 8 (7.6%) | 3 (2.7%) |
| **Clinical TEAE reports; ≥5% of subjects in any group** |
|  Headache | 2 (3.4%) | 4 (6.7%) | 7 (6.7%) | 2 (1.8%) |
|  Insomnia | 3 (5.1%) | 4 (6.7%) | 5 (4.8%) | 8 (7.3%) |
|  Nasopharyngitis | 2 (3.4%) | 3 (5.0%) | 7 (6.7%) | 3 (2.7%) |
|  Pyrexia | 3 (5.1%) | 1 (1.7%) | 3 (2.9%) | 1 (0.9%) |
|  Schizoaffective disorder | 0 (0%) | 4 (6.7%) | 5 (4.8%) | 6 (5.5%) |
|  Upper respiratory tract infection | 1 (1.7%) | 1 (1.7%) | 6 (5.7%) | 3 (2.7%) |
|  Weight increased | 5 (8.5%) | 4 (6.7%) | 9 (8.6%) | 4 (3.6%) |
| **Weight Change, mean (SD) in kg** | +1.4 (4.4) | -0.5 (4.1) | -1.0 (6.7) | -1.0 (4.8) |
| **EPS TEAE reports; >2% of subjects in any group** |
|  Akathisia | 0 (0) | 2 (3.3%) | 5 (4.8%) | 1 (0.9%) |
|  Parkinsonism | 2 (3.4%) | 1 (1.7%) | 1 (1.0%) | 2 (1.8%) |
|  Tremor | 0 (0) | 2 (3.3%) | 2 (1.9%) | 2 (1.8%) |
| **Prolactin-Related Clinical TEAE reports, by sex; ≥2% of subjects in any group** |
| ***Females, number*** | 30 | 30 | 49 | 56 |
|  Amenorrhea | 1 (3.3%) | 2 (6.7%) | 2 (4.1%) | 0 (0) |
|  Galactorrhea | 1 (3.3%) | 1 (3.3%) | 2 (4.1%) | 0 (0) |
|  Libido decreased | 0 (0) | 0 (0) | 1 (2.0%) | 0 (0) |
| ***Males, number*** | 29 | 30 | 56 | 54 |
|  Erectile Dysfunction | 1 (3.5%) | 0 (0) | 0 (0) | 0 (0) |
|  Libido decreased | 0 (0) | 0 (0) | 1 (1.8%) | 0 (0) |
| **Prolactin-Related Laboratory Parameters, by sex** |
| ***Females, number*** | 30 | 30 | 49 | 56 |
|  Hyperprolactinaemia TEAE | 3 (10.0%) | 1 (3.3%) | 0 (0) | 1 (1.8%) |
|  Blood prolactin increased TEAE | 1 (3.3%) | 0 (0) | 3 (6.1%) | 1 (1.8%) |
| Mean (SD) prolactin change from baseline, in μg/L [Number of subjects] | -12.72 (38.908) [22] | -33.40 (43.583) [23] | 4.52 (27.496) [37] | -32.66 (42.851) [42] |
| ***Males, number*** | 29 | 30 | 56 | 54 |
|  Hyperprolactinaemia TEAE | 4 (13.8%) | 0 (0) | 0 (0) | 0 (0) |
|  Blood prolactin increased TEAE | 0 (0) | 0 (0) | 0 (0) | 1 (1.9%) |
| Mean (SD) prolactin change from baseline, in μg/L [Number of subjects] | -1.40 (10.639) [23] | -21.89 (18.5444) [17] | -0.78 (13.657) [44] | -17.39 (18.462) [35] |

EPS=extrapyramidal symptoms; kg=kilograms; SD=standard deviation; TEAE=treatment emergent adverse event.