**Supplemental Table 2. Treatment-Emergent Adverse Events (Safety Population)**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Rollover**  **(Treatment During Double-blind Study)** | | | | | | **De Novo**  **(n=408)** | | **All Participants**  **(N=500)** | |
| **Placebo**  **(n=28)** | | **RBP-7000**  **90 mg**  **(n=31)** | | **RBP-7000**  **120 mg**  **(n=33)** | |
| **N** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **N** | **%** |
| Any TEAE | 21 | 75.0 | 22 | 71.0 | 18 | 54.5 | 306 | 75.0 | 367 | 73.4 |
| Any treatment-related TEAE | 12 | 42.9 | 14 | 45.2 | 12 | 36.4 | 232 | 56.9 | 270 | 54.0 |
| Any serious TEAE | 3 | 10.7 | 3 | 9.7 | 3 | 9.1 | 25 | 6.1 | 34 | 6.8 |
| Any TEAE leading to discontinuation | 6 | 21.4 | 3 | 9.7 | 2 | 6.1 | 47 | 11.5 | 58 | 11.6 |
| TEAE leading to death | 1a | 3.6 | 0 | 0 | 0 | 0 | 3b | 0.7 | 4 | 0.8 |
| Common TEAEs (≥5% of all participants) by MedDRA preferred term | | | | | | | | | | |
| Injection-site pain | 2 | 7.1 | 4 | 12.9 | 7 | 21.2 | 52 | 12.7 | 65 | 13.0 |
| Weight increased | 1 | 3.6 | 0 | 0 | 3 | 9.1 | 60 | 14.7 | 64 | 12.8 |
| Schizophrenia | 4 | 14.3 | 2 | 6.5 | 1 | 3.0 | 32 | 7.8 | 39 | 7.8 |
| Insomnia | 1 | 3.6 | 4 | 12.9 | 3 | 9.1 | 27 | 6.6 | 35 | 7.0 |
| Injection-site nodule | 1 | 3.6 | 1 | 3.2 | 3 | 9.1 | 29 | 7.1 | 34 | 6.8 |
| Akathisia | 2 | 7.1 | 2 | 6.5 | 1 | 3.0 | 25 | 6.1 | 30 | 6.0 |
| Injection-site induration | 0 | 0 | 0 | 0 | 3 | 9.1 | 26 | 6.4 | 29 | 5.8 |
| Upper respiratory tract infection | 1 | 3.6 | 2 | 6.5 | 0 | 0 | 23 | 5.6 | 26 | 5.2 |
| Headache | 0 | 0 | 4 | 12.9 | 1 | 3.0 | 20 | 4.9 | 25 | 5.0 |
| a Death from pulmonary embolism not considered related to the study drug.  b Deaths from cardiac arrest, psychotic disorder, and death (head trauma); none considered related to study drug.  MedDRA, Medical Dictionary for Regulatory Activities, Version 17.0; TEAE, treatment-emergent adverse event. | | | | | | | | | | |