**Supplement Table 3:** **Adverse drug reaction by system organ class and preferred term in the FAS**

| SOC |  | SPP-003 (N = 35) |  | Placebo (N = 39) |
| --- | --- | --- | --- | --- |
|  PT |  | n (%)  | # |  | n (%)  | # |
| Number of subjects with at least one TEAE |  | 15 (42.9) | 32 |  | 8 (20.5) | 12 |
| Metabolism and nutrition disorders |  | 2 (5.7) | 2 |  | 0 |  |
|  Decreased appetite |  | 2 (5.7) | 2 |  | 0 |  |
| Psychiatric disorders |  | 0 |  |  | 1 (2.6) | 1 |
|  Insomnia |  | 0 |  |  | 1 (2.6) | 1 |
| Nervous system disorders |  | 2 (5.7) | 3 |  | 0 |  |
|  Dizziness |  | 1 (2.9) | 1 |  | 0 |  |
|  Headache |  |  1 (2.9) | 1 |  | 0 |  |
|  Taste disorder |  |  1 (2.9) | 1 |  | 0 |  |
| Ear and labyrinth disorders |  |  1 (2.9) | 1 |  | 0 |  |
|  Tinnitus |  |  1 (2.9) | 1 |  | 0 |  |
| Cardiac disorders |  |  1 (2.9) | 1 |  | 0 |  |
|  Sinus tachycardia |  |  1 (2.9) | 1 |  | 0 |  |
| Vascular disorders |  |  1 (2.9) | 1 |  | 0 |  |
|  Hypertension |  |  1 (2.9) | 1 |  | 0 |  |
| Gastrointestinal disorders |  | 9 (25.7) | 14 |  | 3 (7.7) | 3 |
|  Feces discolored |  |  4 (11.4) | 4 |  | 0 |  |
|  Nausea |  |  3 (8.6) | 4 |  | 1 (2.6) | 1 |
|  Abdominal pain upper |  |  2 (5.7) | 3 |  | 0 |  |
|  Abdominal discomfort |  |  1 (2.9) | 1 |  | 1 (2.6) | 1 |
|  Constipation |  |  1 (2.9) | 1 |  | 0 |  |
|  Vomiting |  |  1 (2.9) | 1 |  | 0 |  |
|  Gastritis |  | 0 |  |  | 1 (2.6) | 1 |
| Investigations |  | 8 (22.9) | 10 |  | 5 (12.8) | 8 |
|  Serum ferritin increased |  | 8 (22.9) | 10 |  | 5 (12.8) | 5 |
|  Beta 2 microglobulin increased |  | 0 |  |  | 1 (2.6) | 1 |
|  Beta-N-acetyl-D-glucosaminidase increased |  | 0 |  |  | 1 (2.6) | 1 |
|  Urine output increased |  | 0 |  |  | 1 (2.6)  | 1 |

Adverse drug reactions were collected on or after the date/time of the first dose of the study treatment and on or before 21 days after the date/time of the last dose of the study treatment.

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