**Supplement Table 4:** **Severe TEAEs 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 |  | 6 (17.1) | 8 |  | 7 (17.9) | 8 |
| Infections and infestations |  | 4 (11.4) | 4 |  | 2 (5.1) | 2 |
| Infectious pleural effusion |  | 1 (2.9) | 1 |  | 0 |  |
| Pneumonia |  | 1 (2.9) | 1 |  | 0 |  |
| Sepsis |  | 1 (2.9) | 1 |  | 0 |  |
| Soft tissue infection |  | 1 (2.9) | 1 |  | 0 |  |
| Diverticulitis |  | 0 |  |  | 1 (2.6) | 1 |
| Nasopharyngitis |  | 0 |  |  | 1 (2.6) | 1 |
| Blood and lymphatic system disorders |  | 1 (2.9) | 1 |  | 0 |  |
| Febrile neutropenia |  | 1 (2.9) | 1 |  | 0 |  |
| Metabolism and nutrition disorders |  | 0 |  |  | 3 (7.7) | 3 |
| Hyponatremia |  | 0 |  |  | 2 (5.1) | 2 |
| Decreased appetite |  | 0 |  |  | 1 (2.6) | 1 |
| Ear and labyrinth disorders |  | 1 (2.9) | 1 |  | 0 |  |
| Vertigo |  | 1 (2.9) | 1 |  | 0 |  |
| Vascular disorders |  | 1 (2.9) | 1 |  | 0 |  |
| Deep vein thrombosis | |  | 1 (2.9) | 1 |  | 0 |  |
| Gastrointestinal disorders | |  | 1 (2.9) | 1 |  | 1 (2.6) | 1 |
| Diarrhea | |  | 1 (2.9) | 1 |  | 0 |  |
| Gastritis | |  | 0 |  |  | 1 (2.6) | 1 |
| Investigations | |  | 0 |  |  | 1 (2.6) | 1 |
| Influenza A virus test positive | |  | 0 |  |  | 1 (2.6) | 1 |
| Injury, poisoning, and procedural complications | |  | 0 |  |  | 1 (2.6) | 1 |
| Chemical poisoning | |  | 0 |  |  | 1 (2.6) | 1 |

TEAEs 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.

MedDRA v.