**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.