Supplementary Material

# Table S1. Treatment-emergent adverse events (≥ 2 patients by MedDRA preferred term), treatment-related adverse events, and serious treatment-emergent adverse events in safety population

| **System Organ Class [n(%)]**b **Preferred Term [n(%)]**≥2 patients by preferred term  | **TEAE(N=68)** | **Treatment-related TEAE(N=68)** | **Serious TEAE****(N=68)** |
| --- | --- | --- | --- |
| Patients with Any TEAE [n (%)]\* | 67 (98.5) | 48 (70.6) | 17 (25) |
| Infections and Infestations | 58 (85.3) | 12 (17.6) | 2 (2.9) |
|  Upper Respiratory Tract Infection | 24 (35.3) | 2 (2.9) |  |
|  Nasopharyngitis | 23 (33.8) | 2 (2.9) |  |
|  Coronavirus Infection | 16 (23.5) | 1 (1.5) |  |
|  Bronchitis | 13 (19.1) | 1 (1.5) |  |
|  Gastroenteritis | 7 (10.3) | 0 |  |
|  Influenza | 7 (10.3) | 1 (1.5) |  |
|  Rhinitis | 7 (10.3) | 0 |  |
|  Otitis Media | 5 (7.4) | 1 (1.5) |  |
|  Urinary Tract Infection | 5 (7.4) | 1 (1.5) |  |
|  Conjunctivitis | 4 (5.9) | 1 (1.5) |  |
|  Ear Infection | 4 (5.9) | 0 |  |
|  Oral Herpes | 4 (5.9) | 1 (1.5) |  |
|  Pharyngitis Streptococcal | 4 (5.9) | 0 |  |
|  Pneumonia | 4 (5.9) | 2 (2.9) |  |
|  Respiratory Tract Infection | 4 (5.9) | 1 (1.5) |  |
|  Bronchitis Bacterial | 3 (4.4) | 0 |  |
|  Herpes Zoster | 3 (4.4) | 2 (2.9) |  |
|  Hordeolum | 3 (4.4) | 0 |  |
|  Sinusitis | 3 (4.4) | 0 |  |
|  Eye Infection | 2 (2.9) | 0 |  |
|  Folliculitis | 2 (2.9) | 1 (1.5) |  |
|  Lower Respiratory Infection | 2 (2.9) | 0 | 1 (1.5) |
|  Molluscum Contagiosum | 2 (2.9) | 0 |  |
|  Oral Candidiasis | 2 (2.9) | 0 |  |
|  Pharyngitis | 2 (2.9) | 0 |  |
|  Skin Infection | 2 (2.9) | 0 |  |
|  Tonsillitis | 2 (2.9) | 0 |  |
|  Tooth infection | 2 (2.9) | 0 |  |
|  Viral Infection | 2 (2.9) | 0 | 1 (1.5) |
| General Disorders and Administration Site Conditions | 40 (58.8) | 12 (17.6) | 1 (1.5) |
|  Pyrexia | 33 (48.5) | 3 (4.4) | 1 (1.5) |
|  Fatigue | 10 (14.7) | 6 (8.8) |  |
|  Feeling Hot | 2 (2.9) | 0 |  |
|  Pain | 2 (2.9) | 1 (1.5) |  |
| Investigations | 40 (58.8) | 17 (25.0) | 9 (13.2) |
|  Bacterial Test Positiveb | 14 (20.6) | 2 (2.9) | 9 (13.2) |
|  Blood Iron Decreaseda | 6 (8.8) | 1 (1.5) |  |
|  Blood Lactate Dehydrogenase Increased | 5 (7.4) | 4 (5.9) |  |
|  Coronavirus Test Positive | 5 (7.4) | 0 |  |
|  Bone Density Decreased | 4 (5.9) | 2 (2.9) |  |
|  Serum Ferritin Decreaseda | 4 (5.9) | 1 (1.5) |  |
|  Body Temperature | 3 (4.4) | 0 |  |
|  CD4 Lymphocytes Decreased | 3 (4.4) | 1 (1.5) |  |
|  White Blood Cell Count Decreased | 3 (4.4) | 2 (2.9) |  |
|  Blood Bilirubin Increased | 2 (2.9) | 1 (1.5) |  |
|  Blood Triglycerides Increased | 2 (2.9) | 1 (1.5) |  |
|  Breath Sounds Abnormal | 2 (2.9) | 0 |  |
|  Low Density Lipoprotein Increased | 2 (2.9) | 0 |  |
|  Neutrophil Count Decreased | 2 (2.9) | 2 (2.9) |  |
|  Protein Urine Present | 2 (2.9) | 1 (1.5) |  |
|  Vitamin D Decreased | 2 (2.9) | 0 |  |
|  Weight Increased | 2 (2.9) | 2 (2.9) |  |
| Gastrointestinal Disorders | 38 (55.9) | 12 (17.6) | 1 (1.5) |
|  Vomiting | 21 (30.9) | 6 (8.8) |  |
|  Diarrhea | 19 (27.9) | 2 (2.9) |  |
|  Nausea | 11 (16.2) | 4 (5.9) |  |
|  Abdominal Pain | 5 (7.4) | 1 (1.5) |  |
|  Aphthous Ulcer | 3 (4.4) | 1 (1.5) |  |
|  Constipation | 2 (2.9) | 0 |  |
|  Dyspepsia | 2 (2.9) | 1 (1.5) |  |
|  Gastrointestinal Disorder | 2 (2.9) | 1 (1.5) |  |
|  Toothache | 2 (2.9) | 0 |  |
| Respiratory, Thoracic, and Mediastinal Disorders | 38 (55.9) | 1 (1.5) | 1 (1.5) |
|  Cough | 21 (30.9) | 0 |  |
|  Rhinorrhea | 13 (19.1) | 0 |  |
|  Epistaxis | 7 (10.3) | 0 |  |
|  Oropharyngeal Pain | 7 (10.3) | 0 |  |
|  Nasal Congestion | 5 (7.4) | 0 |  |
|  Productive Cough | 4 (5.9) | 0 |  |
|  Catarrh | 2 (2.9) | 0 |  |
|  Nasal Obstruction | 2 (2.9) | 0 |  |
|  Sneezing | 2 (2.9) | 0 |  |
| Injury, Poisoning, and Procedural Complications | 37 (54.4) | 22 (32.4) | 1 (1.5) |
|  Infusion Related Reactionc | 21 (30.9) | 20\*\* (29.4) |  |
|  Fall | 8 (11.8) | 0 |  |
|  Contusion | 5 (7.4) | 1 (1.5) |  |
|  Ligament Sprain | 4 (5.9) | 0 |  |
|  Skin Abrasion | 3 (4.4) | 0 |  |
|  Face Injury | 2 (2.9) | 0 |  |
|  Forearm Fracture | 2 (2.9) | 0 | 1 (1.5) |
|  Hand Fracture | 2 (2.9) | 0 |  |
|  Procedural Pain | 2 (2.9) | 0 |  |
|  Skin Laceration | 2 (2.9) | 0 |  |
| Skin and Subcutaneous Tissue Disorders | 37 (54.4) | 17 (25.0) |  |
|  Pruritusc | 13 (19.1) | 9 (13.2) |  |
|  Rash | 9 (13.2) | 2 (2.9) |  |
|  Erythema | 8 (11.8) | 3 (4.4) |  |
|  Skin Lesion | 5 (7.4) | 3 (4.4) |  |
|  Alopecia | 4 (5.9) | 1 (1.5) |  |
|  Acne | 3 (4.4) | 0 |  |
|  Dermatitis | 3 (4.4) | 0 |  |
|  Dry Skin | 3 (4.4) | 0 |  |
|  Eczema | 3 (4.4) | 0 |  |
|  Hyperhidrosis | 3 (4.4) | 1 (1.5) |  |
|  Perioral Dermatitis | 2 (2.9) | 0 |  |
|  Rash Erythematous | 2 (2.9) | 0 |  |
|  Skin Depigmentation | 2 (2.9) | 0 |  |
|  Swelling Face | 2 (2.9) | 1 (1.5) |  |
| Metabolism and Nutrition Disorders | 28 (41.2) | 22 (32.4) |  |
|  Iron Deficiencya | 20 (29.4) | 17 (25.0) |  |
|  Increased Appetite | 4 (5.9) | 4 (5.9) |  |
|  Vitamin D Deficiency | 4 (5.9) | 0 |  |
|  Decreased Appetite | 3 (4.4) | 0 |  |
|  Hypocalcemia | 2 (2.9) | 2 (2.9) |  |
| Nervous System Disorders | 28 (41.2) | 9 (13.2) | 2 (2.9) |
|  Headache | 13 (19.1) | 6 (8.8) |  |
|  Dizziness | 6 (8.8) | 2 (2.9) |  |
|  Ataxia | 4 (5.9) | 0 |  |
|  Balance Disorder | 2 (2.9) | 0 |  |
|  Drooling | 2 (2.9) | 0 |  |
|  Paraesthesia | 2 (2.9) | 2 (2.9) |  |
|  Syncope | 2 (2.9) | 0 |  |
| Musculoskeletal and Connective Tissue Disorders | 25 (36.8) | 3 (4.4) |  |
|  Arthralgia | 6 (8.8) | 0 |  |
|  Osteopenia | 5 (7.4) | 3 (4.4) |  |
|  Osteoporosis | 5 (7.4) | 2 (2.9) |  |
|  Foot Deformity | 4 (5.9) | 0 |  |
|  Pain in Extremity | 4 (5.9) | 0 |  |
|  Scoliosis | 4 (5.9) | 0 |  |
|  Joint Swelling | 2 (2.9) | 0 |  |
|  Muscle Spasms | 2 (2.9) | 0 |  |
|  Toe Walking | 2 (2.9) | 0 |  |
| Blood and Lymphatic System Disorders | 14 (20.6) | 9 (13.2) | 1 (1.5) |
|  Anemiad | 6 (8.8) | 2 (2.9) |  |
|  Iron Deficiency Anemiad | 4 (5.9) | 3 (4.4) |  |
|  Neutropenia | 3 (4.4) | 3 (4.4) |  |
|  Leukocytosis | 2 (2.9) | 1 (1.5) |  |
|  Leukopenia | 2 (2.9) | 1 (1.5) |  |
| Eye Disorders | 14 (20.6) | 2 (2.9) |  |
|  Conjunctivitis | 3 (4.4) | 0 |  |
|  Chalazion | 2 (2.9) | 0 |  |
| Psychiatric Disorders | 12 (17.6) | 5 (7.4) |  |
|  Irritability | 5 (7.4) | 2 (2.9) |  |
|  Depressed Mood | 2 (2.9) | 0 |  |
|  Emotional Disorder | 2 (2.9) | 2 (2.9) |  |
|  Enuresis | 2 (2.9) | 0 |  |
| Vascular Disorders | 12 (17.6) | 7 (10.3) | 1 (1.5) |
|  Flushing | 5 (7.4) | 5 (7.4) |  |
|  Hematoma | 2 (2.9) | 0 |  |
|  Hypotension | 2 (2.9) | 1 (1.5) |  |
| Product Issues | 11 (16.2) | 0 |  |
|  Product Contaminationb | 11 (16.2) | 0 |  |
| Neoplasms Benign, Malignant, and Unspecified (Including Cysts and Polyps) | 8 (11.8) | 1 (1.5) | 1 (1.5) |
|  Skin Papilloma | 7 (10.3) | 1 (1.5) |  |
| Ear and Labyrinth Disorders | 7 (10.3) | 1 (1.5) |  |
|  Otorrhea | 2 (2.9) | 0 |  |
| Surgical and Medical Procedures | 5 (7.4) |  | 1 (1.5) |
| Congenital, Familial, and Genetic Disorders | 4 (5.9) | 0 |  |
|  Muscular Dystrophy | 2 (2.9) | 0 |  |
| Reproductive System and Breast Disorders | 3 (4.4) | 3 (4.4) |  |
|  Pruritis Genital | 2 (2.9) | 2 (2.9) |  |

Abbreviations: MedDRA= Medical Dictionary for Regulatory Activities; TEAE=treatment emergent adverse events.

* \*Patients with multiple TEAEs are counted once

a  27 individual patients with low iron values, reported among terms: low ferritin, blood iron decreased (investigations) and iron deficiency (metabolism and nutrition)

b 23 individual patients had positive sterility culture reported in 2 categories: investigations “bacterial test positive” and product issues “product contamination”.

c  Total of 23 patients had pruritus (generalized/anal/genital) during infusion, that was reported as treatment-related. \*\*one patient had an episode of vomiting during the infusion of product which was reported as unrelated to the infusion

d One patient was reported under anemia and iron deficiency anemia