**Supplementary Table 2: Incidence of all-grade TEAE occurring in ≥5% of patients in Part C.**

|  |  |
| --- | --- |
|  | **Part C (TRX518 + gemcitabine)** |
|  | **2 mg/kg load (N=4)** | **4 mg/kg load (N=26)@** | **Total (N=30)** |
| **Any Grade CTCAE v4.03 AE** |
| Any TEAE | 4 (100.0%) | 26 (100.0%) | 30 (100.0%) |
| TRX518 or Gemcitabine Related TEAE | 3 (75.0%) | 26 (100.0%) | 29 (96.7%) |
| TRX518 Related TEAE | 2 (50.0%) | 21 (80.8%) | 23 (76.7%) |
| Gemcitabine Related TEAE | 3 (75.0%) | 26 (100.0%) | 29 (96.7%) |
| TRX518 and Gemcitabine Related TEAE | 2 (50.0%) | 20 (76.9%) | 22 (73.3%) |
| Any SAE | 2 (50.0%) | 12 (46.2%) | 14 (46.7%) |
| Any TESAE | 2 (50.0%) | 11 (42.3%) | 13 (43.3%) |
| TRX518 or Gemcitabine Related TESAE | 0 | 2 (7.7%) | 2 (6.7%) |
| TRX518 Related TESAE | 0 | 1 (3.8%) | 1 (3.3%) |
| Gemcitabine Related TESAE | 0 | 2 (7.7%) | 2 (6.7%) |
| TRX518 and Gemcitabine Related TESAE | 0 | 1 (3.8%) | 1 (3.3%) |
| **AE Summary** |
| Investigations: * Platelet count decreased
* Neutrophil count decreased
* Lymphocyte count decreased
* White blood cell count decreased
* ALT increase
* AST increase
* ALP increase
* LDH increase

Gastrointestinal disorders* Nausea
* Vomiting
* Abdominal pain
* Diarrhea

General disorders and administration site conditions* Fatigue
* Pyrexia
* Asthenia
* Chills
* Night sweats`
* Malaise
* Peripheral edema

Blood and lymphatic system disorders* Anemia
* Thrombocytosis

Metabolism and nutrition disorders* Decreased appetite
* Hypoalbuminemia
* Hyponatremia
* Hypophosphatemia
* Hypercalcemia
* Hypokalemia

Cardiac disorders* Sinus tachycardia

Nervous system disorders* Dysgeusia

Respiratory, thoracic and mediastinal disorders* Dyspnea
* Cough

Vascular disorders* Flushing
* Hypotension

Immune system disorders* Infusion-related reaction

Musculoskeletal disorders* Myalgia

Infections* Sepsis

Skin and subcutaneous tissue disorders* Rash
 | 2 (50.0%)1 (25.0%)1 (25.0%)1 (25.0%)00001 (25.0%)0001 (25.0%)1 (25.0%)000002 (50.0%)01 (25.0%)01 (25.0%)0000000000000 | 7 (26.9%)6 (23.1%)6 (23.1%)7 (26.9%)2 (7.7%)2 (7.7%)1 (3.8%)1 (3.8%6 (23.1%)4 (15.4%)1 (3.8%)1 (3.8%)8 (30.8%)4 (15.4%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)7 (26.9%)1 (3.8%)2 (7.7%)2 (7.7%)2 (7.7%)2 (7.7%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%) | 9 (30.0%)8 (26.7)8 (26.7%)8 (26.7%)2 (6.7%)2 (6.7%)1 (3.3%)1 (3.3%)7 (23.3%)4 (13.3%)1 (3.3%)1 (3.3%)9 (30.0%)5 (16.7%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)9 (30.0%)1 (3.3%)3 (10.0%)2 (6.7%)3 (10.0%)2 (6.7%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%)1 (3.3%) |
| **CTCAE v4.03 Grades 3-4 AEs** |
| Any ≥ Grade 3 TEAE | 4 (100.0%) | 18 (69.2%) | 22 (73.3%) |
| TRX518 or Gemcitabine Related TEAE ≥Grade 3 | 1(25.0%) | 14 (53.8%) | 15 (50.0%) |
| TRX518 Related TEAE ≥Grade 3 | 1 (25.0%) | 7 (26.9%) | 8 (26.7%) |
| Gemcitabine Related TEAE ≥Grade 3 | 1 (25.0%) | 13 (50.0%) | 14 (46.7%) |
| TRX518 and Gemcitabine Related TEAE ≥Grade 3 | 1 (25.0%) | 6 (23.1%) | 7 (23.3%) |
| TRX518 or Gemcitabine Related TESAE ≥Grade 3 | 0 | 2 (7.7%) | 2 (6.7%) |
| TRX518 Related TESAE ≥Grade 3 | 0 | 1 (3.8%) | 1 (3.3%) |
| Gemcitabine Related TESAE ≥Grade 3 | 0 | 2 (7.7%) | 2 (6.7%) |
| TRX518 and Gemcitabine Related TESAE ≥Grade 3 | 0 | 1 (3.8%) | 1 (3.3%) |
| Any TEAE ≥Grade 4 | 0 | 10 (38.5%) | 10 (33.3%) |
| Any TEAE Grade 5 | 0 | 2 (7.7%) | 2 (6.7%) |
| **Reason for Study Discontinuation** |
| Death | 19 (73.1%) | 22 (73.3%) |
| Study terminated by Sponsor | 5 (19.2%) | 5 (16.7%) |
| Withdrawal of ICF | 2 (7.7%) | 3 (10.0%) |
| Other | 0 (0.0%) | 0 (0.0%) |
| @Includes patients enrolled in Part Cesc (N=6) and Part Cexp (N=20)**Abbreviations:** CTCAE, Common Terminology Criteria for Adverse Events; SAE, serious adverse event; TEAE, treatment-emergent adverse event; TESAE, treatment-emergent serious adverse event  |