**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%)  0  0  0  0  1 (25.0%)  0  0  0  1 (25.0%)  1 (25.0%)  0  0  0  0  0  2 (50.0%)  0  1 (25.0%)  0  1 (25.0%)  0  0  0  0  0  0  0  0  0  0  0  0  0 | 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 | | | |