**Supplementary Table 3: Incidence of all-grade TEAE occurring in ≥5% of patients in Parts D, and E.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Part D (TRX518 + pembrolizumab)** | | | **Part E (TRX518 + nivolumab)** | | |
|  | **2 mg/kg load (N=3)** | **4 mg/kg load (N=23)** | **Total (N=26)** | **2 mg/kg load (N=7)** | **4 mg/kg load (N=3)** | **Total (N=10)** |
| **Any Grade CTCAE v4.03 AE** | | | | | | |
| Any TEAE | 3 (100.0%) | 22 (95.7%) | 25 (96.2%) | 7 (100.0%) | 3 (100.0%) | 10 (100.0%) |
| TRX518 or Nivolumab/Pembrolizumab Related TEAE | 2 (66.7%) | 13 (56.5%) | 15 (57.7%) | 4 (57.1%) | 2 (66.7%) | 6 (60.0%) |
| TRX518 Related TEAE | 2 (66.7%) | 12 (52.2%) | 14 (53.8%) | 4 (57.1%) | 2 (66.7%) | 6 (60.0%) |
| Nivolumab/Pembrolizumab Related TEAE | 1 (33.3%) | 12 (52.2%) | 13 (50.0%) | 3 (42.9%) | 2 (66.7%) | 5 (50.0%) |
| TRX518 and Nivolumab/Pembrolizumab Related TEAE | 1 (33.3%) | 11 (47.8%) | 12 (46.2%) | 3 (42.9%) | 2 (66.7%) | 5 (50.0%) |
| Any SAE | Pending |  |  | 1 (14.3%) | 1 (33.3%) | 2 (20.0%) |
| Any TESAE | 1 (33.3%) | 7 (30.4%) | 8 (30.8%) | 1 (14.3%) | 1 (33.3%) | 2 (20.0%) |
| TRX518 or Nivolumab/Pembrolizumab Related TESAE | 1 (33.3%) | 5 (21.7%) | 6 (23.1%) | 1 (14.3%) | 1 (33.3%) | 2 (20.0%) |
| TRX518 Related TESAE | 0 | 0 | 0 | 1 (14.3%) | 0 | 1 (10.0%) |
| Nivolumab/Pembrolizumab Related TESAE | 0 | 0 | 0 | 1 (14.3%) | 0 | 1 (10.0%) |
| TRX518 and Nivolumab/Pembrolizumab Related TESAE | 0 | 0 | 0 | 1 (14.3%) | 0 | 1 (10.0%) |
| **AE Summary** | | | | | | |
| General disorders and administration site conditions   * Fatigue * Chills * Fever * Dyspnea   Investigations:   * Anemia decreased * ALT increase * AST increase * LDH increase * Triglyceride increase   Gastrointestinal disorders   * Nausea * Vomiting * Diarrhea   Cardiac disorders   * Atrial fibrillation   Nervous system disorders   * Dysgeusia   Musculoskeletal disorders   * Arthralgia   Immune system disorders   * Hypothyroidism * Myositis   Renal and urinary disorders   * Proteinuria * Hematuria   Respiratory, thoracic and mediastinal disorders   * Nasal congestion   Skin and subcutaneous tissue disorders   * Rash * Oncychoclasis | 0  0  0  0  0  0  0  0  0  0  0  0  0  0  0  0  0  1 (33.3%)  0  0  0  0 | 5 (21.7%)  1 (4.3%)  1 (4.3%)  1 (4.3%)  0  1 (4.3%)  1 (4.3%)  1 (4.3%)  1 (4.3%)  1 (4.3%)  0 (0.0%)  1 (4.3%)  0  2 (8.7%)  0  2 (8.7%)  1 (4.3%)  0  0  0 0  6 (26.1%)  0 | 5 (19.2%)  1 (3.8%)  1 (3.8%)  1 (3.8%)  0  1 (3.8%)  1 (3.8%)  1 (3.8%)  1 (3.8%)  1 (3.8%)  0 (0.0%)  1 (3.8%)  0  2 (7.7%)  0  2 (7.7%)  1 (3.8%)  1 (3.8%)  0  0  6 (23.1%)  0 | 1 (14.3%)  0  1 (14.3%)  0  1 (14.3%)  0  0  0  0 (0.0%)  1 (14.3%)  1 (14.3%)  0  1 (14.3%)  0  0  0  0  1 (14.3%)  0  0  0  0 | 0  0  0  0  0  0  0  0  0  0  0  0  0  0  0  0  0  0  0  1 (33.3%)  0  1 (33.3%) | 1 (10.0%)  0  1 (10.0%)  0  1 (10.0%)  0  0  0  0  1 (10.0%)  1 (10.0%)  0  1 (10.0%)  0  0  0  0  1 (10.0%)  0  1 (10.0%)  0  1 (10.0%) |
| **CTCAE v4.03 Grades 3-4 AEs** | | | | | |  |
| Any ≥ Grade 3 TEAE | 1 (33.3%) | 8 (34.8%) | 9 (34.6%) | 3 (42.9%) | 1 (33.3%) | 4 (40.0%) |
| TRX518 or Nivolumab/Pembrolizumab Related TEAE ≥Grade 3 | 0 | 0 | 0 | 1 (14.3%) | 0 | 1 (10.0%) |
| TRX518 Related TEAE ≥Grade 3 | 0 | 0 | 0 | 1 (14.3%) | 0 | 1 (10.0%) |
| Nivolumab/Pembrolizumab Related TEAE ≥Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| TRX518 and Nivolumab/Pembrolizumab Related TEAE ≥Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| TRX518 or Nivolumab/Pembrolizumab Related TESAE ≥Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| TRX518 Related TESAE ≥Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| Nivolumab/Pembrolizumab Related TESAE ≥Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| TRX518 and Nivolumab/Pembrolizumab Related TESAE ≥Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| Any TEAE ≥Grade 4 | 0 | 0 | 0 | 0 | 1 (33.3%) | 1 (10.0%) |
| Any TEAE Grade 5 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Reason for Study Discontinuation** | | | | | | |
| Death | | | 9 (34.6%) |  | | 7 (70.0%) |
| Study terminated by Sponsor | | | 16 (61.5%) |  | | 3 (30.0%) |
| Withdrawal of ICF | | | 1 (3.8%) |  | | 0 (0.0%) |
| Other | | | 0 (0.0%) |  | | 0 (0.0%) |
| **Abbreviations:**  CTCAE, Common Terminology Criteria for Adverse Events; SAE, serious adverse event; TEAE, treatment-emergent adverse event; TESAE, treatment-emergent serious adverse event | | | | | | |