**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
 | 000000000000000001 (33.3%)0000 | 5 (21.7%)1 (4.3%)1 (4.3%)1 (4.3%)01 (4.3%)1 (4.3%)1 (4.3%)1 (4.3%)1 (4.3%)0 (0.0%)1 (4.3%)02 (8.7%)02 (8.7%)1 (4.3%)000 06 (26.1%)0 | 5 (19.2%)1 (3.8%)1 (3.8%)1 (3.8%)01 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)1 (3.8%)0 (0.0%)1 (3.8%)02 (7.7%)02 (7.7%)1 (3.8%)1 (3.8%)006 (23.1%)0 | 1 (14.3%)01 (14.3%)01 (14.3%)0000 (0.0%)1 (14.3%)1 (14.3%)01 (14.3%)00001 (14.3%)0000 | 00000000000000000001 (33.3%)01 (33.3%) | 1 (10.0%)01 (10.0%)01 (10.0%)00001 (10.0%)1 (10.0%)01 (10.0%)00001 (10.0%)01 (10.0%)01 (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 |