TRX518 Single-Dose Safety Study Results

### Key Study Criteria

- **Efficacy:** Fatality was monitored at 17 weeks in cohort 1 and at 13 weeks in cohort 2, 3, and 5.
- **Safety:** Treatment emergent adverse events were monitored during the entire study period.
- **Immunogenicity:** Pre- and post-treatment imaging was performed on 31 of 41 patients.
- **Pharmacokinetics:** No reported autoimmune TEAE.
- Most common TRX-518 related TEAEs include fatigue (n=4), pruritus (n=3), and anorexia, proteinuria, rash and flushing (n=2).

### Immunogenicity

- **Pharmacokinetics and Pharmacodynamics:**
  - **TRX518 was well tolerated as a single-dose in patients with refractory solid tumors.**
  - **TRX518 was the first anti-GITR agonist tested in humans.**
  - **4 of 21 patients with ADA appeared to have accelerated clearance of TRX518, but the impact was modest.**
  - **However, 21 of 29 evaluable patients (72%) had detectable anti-drug antibody (ADA) responses, but with low titer as compared to the unexposed population.**

### Efficacy

- **Efficacy and Immunogenicity:**
  - **Efficacy was evaluated with the immune related response criteria.**
  - **Immunogenicity was evaluated with the immune related response criteria.**

### Discussion & Conclusions

- **TRX518 was well tolerated as a single-dose in patients with refractory solid tumors.**
- **TRX518 was the first anti-GITR agonist tested in humans.**
- **4 of 21 patients with ADA appeared to have accelerated clearance of TRX518, but the impact was modest.**
- **However, 21 of 29 evaluable patients (72%) had detectable anti-drug antibody (ADA) responses, but with low titer as compared to the unexposed population.**

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**References**

1. Walsh R, et al. [18].
2. Reardon DA, et al. [5].
4. Reardon DA, et al. [5].
6. Reardon DA, et al. [5].
8. Reardon DA, et al. [5].