A Phase 1 Study of TSR-022, an Anti-TIM-3 Monoclonal Antibody, in Combination with TSR-042 (Anti-PD-1) in Patients with Colorectal Cancer and Post-PD-1 NSCLC and Melanoma

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BACKGROUND

- TIM-3 is a homolog of CTLA-4 and is expressed on tumor-infiltrating lymphocytes
- TIM-3 is a potent and selective anti-TIM-3 antibody that is being developed in combination with the anti-PD-1 antibody TSR-042

METHODS

- AMBER is a phase 1 dose-escalation study enrolling 2 cohorts of patients who have progressed on a prior anti-PD-1 treatment
- Baseline Ctx
  - Age
  - Sex
  - Race
  - ECOG performance status
  - Number of prior lines of therapy
  - Type of tumor
  - NY-ESO1
  - CD274

RESULTS

- Four had a confirmed PR (3 by RECIST and 1 by irRECIST; 3 ongoing)
- 900 mg dose required for effective exposure throughout dose interval (Figure 5)
- TSR-022 in combination with TSR-042 demonstrated clinical activity in post-PDL-1 NSCLC; a dose response trend was observed (Figures 6 and 7)

CONCLUSIONS

- TSR-022 is a potent and selective anti-TIM-3 antibody that is being developed in combination with the anti-PD-1 antibody TSR-042
- Treatment with TSR-022 in combination with TSR-042 was well tolerated
- TSR-022 in combination with TSR-042 demonstrated clinical activity in patients who have progressed on prior anti-PD-1 treatment
- Objective responses observed were in PD-L1 positive (TPS ≥1%) patients, indicating the potential for biomarker enrichment
- A dose response trend was observed, with greater evidence of antitumor activity in the population receiving the 900 mg dose compared to the 300 mg dose
- TSR-022 PK was dose proportional with the 900 mg dose required for effective exposure throughout dose interval in most patients. Enrollment at the 900 mg dose level is ongoing in the NSCLC cohort.