Oral or Poster Presentation Abstract Submission

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A PHASE I STUDY OF TST001 (ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY) IN PATIENTS WITH SOLID TUMORS

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What is your preferred presentation method?: Oral/Poster
Do you want to apply for travel grants?: No

Objectives: Primary objectives are to evaluate the safety and tolerability, to identify MTD and recommended phase 2 dose (RP2D). Secondary objectives include the assessment of pharmacokinetic parameter, immunogenicity, and preliminary anti-cancer activity.

Methods: This phase I clinical trial enrolls patients with advanced or metastatic solid tumors who progressed on or after standard treatments. In the dose escalation phase, patients without preselection of tumor CLDN18.2 expression were given increasing doses of TST001 intravenously every 3 weeks (Q3W) using a 3+3 design.

Results: As of Sept. 7, 2021, 11 patients had been treated at the dose levels of 3, 6, and 10 mg/kg Q3W. Nine patients were DLT evaluable with no DLT reported and MTD has not been reached. TST001 demonstrated a roughly linear PK profile as both Cmax and AUC increased proportionally across the dose range following the first dose. No drug accumulation was observed in Q3W cohort. 10 mg/kg Q3W was designated as RP2D for further expansion study and three additional patients were enrolled into the expansion phase at the 10 mg/kg Q3W dose. The most common AEs (>20%) included nausea (64%), vomiting (50%), anemia (43%), hypoalbuminemia (29%), abdominal distension (21%), constipation (21%). 5 patients experienced Grade 3 AEs, including blood pressure increased, bilirubin conjugated increased, hyponatremia, nausea and vomiting, pulmonary embolism. Two patients experienced 3 SAEs including hypoalbuminemia, jaundice cholestatic; pulmonary embolism. No treatment related Grade 4 or 5 event was reported. One patient with CLDN18.2 overexpression gastric signet ring cell carcinoma who progressed on multiple lines of chemotherapies, anti-PD1 and anti-VEGF therapies in the 6 mg/kg cohort achieved a confirmed partial response at week 12.

Conclusions: TST001 demonstrated a manageable & tolerable safety profile in patients with advanced solid tumors and preliminary anti-tumor activity in a heavily pretreated gastric cancer patient expressing CLDN18.2.