TPS3164 **Poster Session**

TUB-030, a novel ADC targeting 5T4: A phase I/IIa multi-center, first-in-human clinical trial (5-STAR 1-01) in patients with advanced solid tumors.

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Background: TUB-030 is a novel antibody-drug conjugate (ADC) targeting 5T4, an oncofetal antigen expressed in various solid tumors with limited expression in healthy tissues. TUB-030 leverages optimized biophysical properties, an effector-silenced antibody, and an exatecan payload to maximize the therapeutic index and minimize off-target toxicities. Preclinical studies demonstrated potent anti-tumor activity, including long-lasting tumor regression at doses as low as 1 mg/kg and durable responses even in tumors with low 5T4 expression. **Methods:** 5-STAR 1-01 is a multicenter, first-in-human dose escalation and dose optimization Phase I/IIa clinical trial designed to investigate safety, tolerability, pharmacokinetics (PK), and efficacy of the anti-5T4 ADC TUB-030 in patients with advanced and metastatic solid tumors. Eligible patients have one of the following tumor types: head and neck squamous cell carcinomas (HNSCC), non-small-cell lung cancer (NSCLC), small cell lung cancer, pleural mesothelioma, triple-negative breast cancer, HR+/HER2- breast cancer, esophageal cancer, gastric cancer, pancreatic adenocarcinoma, colorectal cancer, bladder cancer, prostate cancer, cervical cancer, osteosarcoma, or soft tissue sarcomas and must have exhausted available standard-of-care therapies. Phase I is an open-label, single-arm dose escalation trial, with administration every 21 days. Dose escalation follows an accelerated titration design (ATD) transitioning to Bayesian optimal interval (BOIN) upon predefined toxicity thresholds. Backfill cohorts are planned in NSCLC and HNSCC to further evaluate the safety and efficacy profile at, or near, the maximum tolerated dose (MTD). Primary endpoints include safety and tolerability of TUB-030 as monotherapy, determination of the MTD and the recommended phase II doses; secondary endpoints assess pharmacokinetics, immunogenicity, and preliminary clinical activity using RECIST v1.1 criteria. Exploratory endpoints include analysis of circulating tumor DNA. In phase IIa, dose-optimization will evaluate two dose levels in select indications in order to identify the optimal dose for further development. Enrollment of approximately 130 patients across the US and Canada is planned, with dose escalation currently underway. This study investigates TUB-030, a novel 5T4 targeted ADC as a therapy for advanced/metastatic solid tumors. Clinical trial information: NCT06657222. Research Sponsor: None.