TPS3162 **Poster Session**

Phase I multicenter, open-label, dose escalation study of T-1201, a small molecule drug conjugate, to assess safety, pharmacokinetics, and antitumor activity in advanced solid tumors.

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Background: Phosphatidylserine (PS) is a phospholipid critical for maintaining cell membrane integrity and functionality. In rapidly proliferating cancer cells, PS translocates to the outer leaflet of the membrane, making it a promising biomarker and therapeutic target for cancer treatment. The investigational drug T-1201 is a proprietary small molecule drug conjugate combining a bioactive topoisomerase I inhibitor, SN-38, with Zn-DPA complexes, which exhibit high affinity for PS. Preclinical studies have demonstrated T-1201's in-vivo antitumor activity across multiple human tumor xenograft models. This study represents the first clinical evaluation of T-1201 in humans. **Methods:** The primary objectives of this phase I study are to evaluate the safety profile of T-1201, determine dose-limiting toxicities (DLTs), establish the maximum tolerated dose (MTD), and identify the recommended phase II dose (RP2D). Secondary objectives include characterization of pharmacokinetics (PK) and assessment of antitumor activity for T-1201. The study comprises three dose-escalation parts. In Part A, T-1201 is administered intravenously once every four weeks (Q4W), starting at 18 mg/m^2 during Cycle 1. From Cycle 2 onward, the dosing interval can be adjusted to once every two weeks (Q2W) at the investigator's discretion, subject to agreement with the Sponsor. When switching to the Q2W schedule, the dose level is halved compared to the Q4W dose. Each treatment cycle spans four weeks, with dose escalation proceeding via a single-patient cohort design (100% dose increments) initially, transitioning to a modified 3+3 design (40% dose increments) based on DLTs observed in Cycle 1. In Part B, T-1201 is administered intravenously Q2W in a 28-day treatment cycle, starting at 100 mg/m^2, which represents half of the MTD identified in Part A. In Part C, each treatment cycle is reduced to 21 days, with the starting dose not exceeding the highest dose level deemed safe by the Safety Review Committee (SRC) in Part B. Eligible patients are ≥18 years of age, have an Eastern Cooperative Oncology Group (ECOG) performance status of 0–1, and possess radiographically or clinically evaluable tumors. As of now, 27 patients have been enrolled in the Part A dose-escalation stage. This study is registered with ClinicalTrials.gov (NCT04866641). Clinical trial information: NCT04866641. Research Sponsor: Taivex Therapeutics corporation.

Dose escalation/de-escalation rule for the BOIN design.

Number of subjects treated at the current dose*	3	4	5	6	7	8	9
Escalate if # of DLT ≤	0	1	1	1	1	2	2
Stay at current dose if # of DLT =	1	NA	NA	2	2	3	3
De-escalate if # of DLT ≥	2	2	2	3	3	4	4
Eliminate if # of DLT ≥	3	3	4	4	5	5	6

*The enrollment may stop when one of the following criteria is met: The planned sample size has been reached; at least 9 subjects have been treated and evaluable for DLT at one dose level; or all doses explored appear to be overly toxic, and the MTD cannot be determined.