TPS2703 **Poster Session**

A first-in-human phase 1 clinical trial of INI-4001, a novel TLR7/8 agonist, in patients with advanced solid tumors.

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Background: Inimmune has developed INI-4001, a novel TLR7/8 agonist as an immunotherapy treatment for cancer. Pre-clinically, the lead formulation of INI-4001 was able to eliminate Lewis Lung Carcinoma (LLC) flank tumors in mice after just two treatments. Moreover, INI-4001 slowed the growth of MC38 and B16F10 tumors and synergized when combined with anti-PD-1 therapy, leading to an increased cure rate in both MC38 and B16F10 flank tumors in mice when both drugs were used compared to either treatment alone. In July of 2024, we dosed our first patient in a Phase 1 clinical trial in patients with advanced solid tumors. **Methods:** INI-4001 will be evaluated in a Phase Ia/Ib, open-label, dose-escalation, and dose expansion study. This study will be conducted in two parts: Phase Ia (dose escalation) and Phase Ib (dose expansion). Phase Ia will initially seek to establish the MTD or OBD of INI-4001 administered as monotherapy. Using a BOIN design, we have planned six ascending 1-3-subject cohorts with weekly dosing on continuous 21-day cycles. Imaging shall occur after each 3 cycles, and combination therapy with a checkpoint inhibitor is allowable under certain conditions after 3 cycles of monotherapy. Combination with checkpoint inhibitor is allowed if the subject has progressed or achieved stable disease according to iRECIST criteria and has a tumor type for which a checkpoint inhibitor is approved. Following identification of the MTD or OBD, Phase 1b allows any dose level at or below the MTD to be expanded with up to 20 additional subjects to further explore the safety, PK, PD, and preliminary efficacy of INI-4001 alone or as combination therapy. Currently in Phase Ia, Cohorts 1, 2, and 3 have been completed without DLT. Enrollment to Cohort 4 will begin in February 2025. INI-4001 may continue as monotherapy or combination as long as the subject receives benefit. Following cessation of INI-4001, patients will be requested to participate in long-term follow-up to assess overall survival. Clinical trial information: NCT06302426. Research Sponsor: None.