AdvanTIG-204: Anti-TIGIT monoclonal antibody ociperlimab plus anti-PD-1 mAb tislelizumab plus concurrent chemoradiotherapy in patients with untreated limited-stage small cell lung cancer

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**Background:**

Patients (pts) with limited-stage small cell lung cancer (LS-SCLC) have a modest prognosis (5-year survival rate: 25–30%) and require more effective therapies. T-cell immunoreceptor with immunoglobulin and tyrosine-based inhibitory motif domains (TIGIT) is a co-inhibitory immune checkpoint receptor upregulated on T-cells and natural killer cells in multiple solid tumors, which can inhibit anticancer immune responses. Dual targeting of tumors with anti-TIGIT and anti-programmed cell death protein 1 (PD-1) produces synergistic immune cell activation and enhanced antitumor activity in preclinical models. Ociperlimab (OCI) is a humanized, monoclonal antibody (mAb) that binds TIGIT with high specificity and affinity, blocking interaction with its ligands on tumor cells. Tislelizumab (TIS) is an anti-PD-1 mAb engineered to minimize binding to Fc-gamma receptors on macrophages to abrogate antibody-dependent phagocytosis, a potential resistance mechanism to anti-PD-1 therapy.

**Methods:**

AdvanTIG-204 is a Phase 2, randomized, multicenter, open-label study (NCT04952597). Approximately 120 treatment-naïve pts with LS-SCLC will be randomized 1:1:1 to receive either OCI 900 mg intravenously (IV) + TIS 200 mg IV combined with concurrent chemoradiotherapy (cCRT) for 4 cycles, followed by OCI 900 mg + TIS 200 mg (Arm A), TIS 200 mg IV combined with cCRT for 4 cycles, followed by TIS 200 mg IV (Arm B), or cCRT only for 4 cycles (Arm C). OCI and TIS will be administered once every 3 weeks for ≤ 12 months, or until disease progression, unacceptable toxicity, death or withdrawal of consent, whichever occurs first. Radiotherapy will start early within Cycle 1 or 2 of systemic therapy. Pts will be stratified by disease stage (I/II vs III). The primary endpoint is progression-free survival as assessed by the investigator (RECIST v1.1) in the intent-to-treat population. Secondary endpoints include complete response rate, overall response rate, duration of response, overall survival (all investigator-assessed), correlation of programmed death-ligand 1 and TIGIT expression with efficacy endpoints, and

safety. Exploratory endpoints include, but are not limited to, biomarker evaluation, health-related quality of life, and circulating tumor DNA. Study enrollment is ongoing.