Phase 3 Trial in Progress of Platinum-Containing Combination Chemotherapy With or Without Tislelizumab as First-line Therapy in Patients With Untreated Extensive-Stage Small Cell Lung Cancer (SCLC)

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Background First-line standard of care for patients with untreated extensive-stage SCLC is platinum (cisplatin or carboplatin) plus etoposide. Despite initial response rates of 60-70% in patients treated with platinum, the prognosis in these patients remains poor, with median overall survival of approximately 9-11 months and a 2-year survival rate of <5%. As such, there is a significant unmet clinical need for new agents that can be combined with established treatments. Tislelizumab is an investigational monoclonal antibody with high affinity and specificity for programmed death protein-1 (PD-1) and was engineered to minimize binding to FcγR on macrophages to abrogate antibody-dependent phagocytosis, a mechanism of T-cell clearance and potential resistance to anti-PD-1 therapy. Prior reports have shown that tislelizumab, as monotherapy or in combination with platinum-containing chemotherapy, was generally well tolerated and demonstrated preliminary antitumor activity in patients with advanced solid tumors, including extensive-stage SCLC.

Methods This randomized, double-blind, phase 3 study compares tislelizumab plus etoposide and platinum with placebo plus etoposide and platinum as first-line treatment for patients with untreated extensive-stage SCLC. Approximately 364 patients across 50 sites in China will be randomized 1:1 during the induction phase to receive tislelizumab (200 mg IV Q3W) or placebo (IV Q3W) in combination with chemotherapy consisting of etoposide (100 mg/m² IV Days 1-3 of each 21-day cycle) and platinum (cisplatin 75 mg/m² IV Q3W or carboplatin AUC 5 IV Q3W) for 4 cycles. Maintenance consists of tislelizumab or placebo Q3W and will continue until disease progression, loss of clinical benefit, unacceptable toxicity, or withdrawal of informed consent. Investigator-assessed progression-free survival and overall survival in the intent-to-treat analysis set are the primary endpoints. Additional efficacy endpoints will include objective response rate, duration of response, disease control rate; quality of life outcomes and safety/tolerability will also be evaluated.