AdvanTIG-105: Phase 1b Dose-Expansion Study of Ociperlimab plus Tislelizumab with Chemotherapy in Patients With Metastatic Squamous and Nonsquamous Non-Small Cell Lung Cancer

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Background: TIGIT inhibitor plus a PD-1 antibody is a promising combination which shows potent efficacy in solid tumors. AdvanTIG-105 is an open-label dose-escalation/-expansion study designed to assess the safety and preliminary antitumor activity of ociperlimab (investigational anti-TIGIT mAb) plus tislelizumab (clinical-stage anti-PD-1 mAb) in patients with metastatic unresectable solid tumors (NCT04047862). In the dose-escalation phase, ociperlimab plus tislelizumab was well tolerated, preliminary antitumor activity was observed, and the RP2D of ociperlimab (900 mg IV Q3W) plus tislelizumab (200 mg IV Q3W) was established. Here, we report results from NSCLC dose-expansion cohorts of the AdvanTIG-105 study.

Methods: Treatment-naïve adult patients with histologically/cytologically confirmed metastatic squamous NSCLC (Cohort 1 [C1]) or nonsquamous NSCLC with *EGFR/ALK/ROS-1* wild-type tumors (Cohort 2 [C2]) were enrolled.

Patients in C1 received the RP2D of ociperlimab plus tislelizumab with paclitaxel/*nab*-paclitaxel plus carboplatin; patients in C2 received the RP2D of ociperlimab plus tislelizumab with pemetrexed plus cisplatin/carboplatin until disease progression, intolerable toxicity, or withdrawal of consent. Primary endpoint was investigator-assessed ORR per RECIST v1.1; safety/tolerability profile was a secondary endpoint.

Results: As of March 18, 2022, 84 patients were enrolled (C1: n=41; C2: n=43). The median study follow-ups were 17.7 weeks (range 1.1-42.6) and 15.0 weeks (3.0-51.1) in C1 and C2, respectively. Overall, 76 patients were evaluable for efficacy. In C1, confirmed ORR was 45.9% (95% CI: 0.3, 0.6) and 25.6% (95% CI: 0.1, 0.4) in C2. Overall, 81 patients (96.4%) experienced ≥1 adverse event (AE), and 48 patients (57.1%) had grade ≥3 AEs. Serious AEs occurred in 26 patients (31.0%). Most common AEs were anemia (41.7%), neutrophil count decreased (33.3%), and white blood cell count decreased (33.3%).

Conclusion: Ociperlimab 900 mg IV Q3W plus tislelizumab 200 mg IV Q3W in combination with chemotherapy was generally well tolerated and showed antitumor activity in patients with treatment-naïve metastatic squamous/nonsquamous NSCLC.