AdvanTIG-105: Phase 1b Dose-Expansion Study of Ociperlimab Plus Tislelizumab in Patients with Metastatic NSCLC

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Background: Combination of anti-TIGIT/anti-PD-1 antibodies is a promising therapy for NSCLC. AdvanTIG-105 is a dose-escalation/-expansion study designed to assess the safety and preliminary antitumor activity of ociperlimab (investigational anti-TIGIT mAb) with tislelizumab (clinical-stage anti-PD-1 mAb) in patients with advanced, metastatic unresectable solid tumors (NCT04047862). Here, we report results from a dose-expansion cohort of AdvanTIG-105.

Methods: Treatment-naïve adult patients with histologically or cytologically confirmed metastatic squamous or nonsquamous NSCLC with PD-L1-positive (tumor cell [TC] ≥1% by VENTANA PD-L1 [SP263] Assay) and nonsquamous

patients with *EGFR/ALK/ROS-1* wild-type tumors were enrolled. Patients received the RP2D of ociperlimab 900mg IV Q3W plus tislelizumab 200mg IV Q3W until disease progression, intolerable toxicity, or withdrawal of consent. Primary endpoint was investigator-assessed ORR per RECIST v1.1.

Results: As of 5 April 2022, 40 patients (median age: 65.0 years [range 46-81]) were enrolled; median study follow-up was 28.1 weeks (range 3.1-61.7). Overall, ORR in the efficacy-evaluable set (N=39) was 53.8% (95% CI: 37.2, 69.9); DCR was 89.7% (95% CI: 75.8, 97.1). In patients with PD-L1 TC ≥50% (n=14), ORR was 71.4% (95% CI: 41.9, 91.6), and 44.0% (95% CI: 24.4, 65.1) in patients with PD-L1 TC 1-49% (n=25). In the safety analysis set (N=40), 38 patients (95.0%) experienced ≥1 AE and 11 (27.5%) had grade ≥3 AEs. Most common AEs were pruritus (32.5%), pyrexia (30.0%), rash (20.0%), and decreased appetite (20.0%). Serious AEs occurred in 10 patients (25.0%); AEs leading to treatment discontinuation occurred in three patients (7.5%). An AE leading to death (cerebral infarction) occurred in one patient, but the event was not considered to be related to the study drugs.

Conclusion: Combination of ociperlimab 900mg plus tislelizumab 200mg IV Q3W was well tolerated and showed preliminary antitumor activity in patients with treatment-naïve metastatic squamous or nonsquamous NSCLC with