**Tislelizumab in Chinese Patients With Non-Small Cell Lung Cancer (NSCLC)**

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**Background:** Tislelizumab, a monoclonal anti-PD-1 antibody, was specifically 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. In preliminary reports from this phase 1/2 study (NCT04068519), tislelizumab monotherapy was generally well tolerated and demonstrated antitumor activity in Chinese patients (pts) with advanced solid tumors. We now present data from pts with NSCLC.

**Methods:** Eligible pts progressed on, or were intolerant to, their last standard antitumor treatment and were anti-PD-1/L1 therapy treatment-naïve. Patients received intravenous tislelizumab 200 mg every 3 weeks until loss of clinical benefit or unacceptable toxicity. PD-L1 positivity was defined as ≥10% tumor cell PD-L1 membrane staining using the VENTANA PD-L1 (SP263) assay. Key endpoints included antitumor response, overall survival (OS), and safety/tolerability.

**Results:** As of 01 December 2018, 56 pts with NSCLC (nonsquamous, n=31 [55%]; squamous, n=25 [45%]) were enrolled; 53 (95%) had metastatic disease, 23 (41%) never smoked, and 1 pt each had an *EGFR* mutation or *ALK* rearrangement. Patients were heavily pretreated, with 16 pts (29%) receiving ≥3 lines of prior systemic therapy. The most common treatment-related AEs (TRAEs) were increased AST (n=14; 25%) and ALT (n=13; 23%). Increased AST (n=3; 5%) and ALT (n=2; 4%) were the only grade ≥3 TRAEs occurring in ≥2 pts. Immune-related AEs (irAEs) occurred in 12 pts (21%) and were generally of low severity, including 1 pt with grade 2 pneumonitis; 4 pts (7%) had a grade ≥3 irAE. Objective response rate (ORR) was 18% (95% CI: 8.9, 30.4). ORRs were 17% (95% CI: 4.7, 37.4) and 19% (95% CI: 7.5, 37.5) in PD-L1-positive (n=24) and PD-L1-negative (n=31) pts, respectively. With a median follow-up of 14.6 mo (95% CI: 12.0, 15.6), median OS was not reached. Updated data with ≥2 yrs of follow-up will be presented, including OS.

**Conclusions:** Tislelizumab was generally well tolerated and demonstrated antitumor activity in NSCLC pts regardless of PD-L1 expression. Tislelizumab is being evaluated as a single agent or with chemotherapy in phase 3 NSCLC studies (NCT03358875, NCT03594747, NCT03663205).