Tislelizumab in Chinese Patients (Pts) With Non-Small Cell Lung Cancer (NSCLC) and Nasopharyngeal Carcinoma (NPC)

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Background Tislelizumab, an investigational monoclonal antibody with high affinity and specificity for PD-1, was engineered to minimize binding to FcγR on macrophages in order to abrogate antibody-dependent phagocytosis, a mechanism of T-cell clearance and potential resistance to anti-PD-1 therapy. Preliminary reports from this study (CTR20160872) showed single-agent tislelizumab was generally well tolerated and had antitumor activity in pts with advanced solid tumors; updated data from pts with NSCLC and NPC are presented.

Methods Eligible pts had histologically or cytologically confirmed advanced tumors and progressed from/were intolerable to their last standard antitumor treatment; pts must not have received prior anti-PD-(L)1 therapy. Antitumor response was assessed by RECIST v1.1, survival was estimated by Kaplan-Meier analysis, and safety/tolerability was examined by monitoring adverse events (AEs). The safety analysis set (SAF) included all pts receiving ≥1 dose of tislelizumab.

Results As of 01 Dec 2018, 56 pts with NSCLC and 21 with NPC were treated with tislelizumab 200 mg IV Q3W. Most pts were male (71%, NSCLC; 81%, NPC) and were heavily pretreated; many had never smoked (41%, NSCLC; 67%, NPC). Median ages were 58 and 48 yr, respectively. Across the study (n=300), the most common treatment-related AEs (TRAEs) were anemia (23%) and increased AST (22%); the most common grade ≥3 TRAEs were increased GGT (4%), anemia (3%), and increased AST (3%). One grade 5 AE (brain edema) was considered possibly related to tislelizumab. Antitumor activity and survival are summarized (**Table**; SAF). Despite a long median follow-up (NSCLC: 9.0 mo, range: 0.2-18.5; NPC: 11.7 mo, range: 4.9-15.7), overall survival remains immature.

Conclusions Tislelizumab was generally well tolerated and demonstrated antitumor activity in pts with advanced solid tumors.

	NSCLC (n=56)	NPC (n=21)
Remaining on treatment, n (%)	16 (28.6)	9 (42.9)
Prior anticancer regimens, n (%)		
1	17 (30.3)	6 (28.6)
2	14 (25.0)	5 (23.8)
3	14 (25.0)	1 (4.8)
≥4	10 (17.9)	9 (42.9)

Confirmed ORR, % (95% CI)	17.9 (8.9-30.4)	42.9 (21.8-66.0)
Median PFS, mo (95% CI)	4.0 (2.1-8.1)	10.4 (4.2-10.5)
Probability of OS at 1 yr (95% CI)	0.6 (0.4-0.7)	0.6 (0.3-0.8)