Tislelizumab in Chinese Patients (Pts) With Esophageal Cancer (EC), Gastric Cancer (GC), Hepatocellular Carcinoma (HCC), and Microsatellite Instability-High/Mismatch Repair Deficient (MSI-H/dMMR) Tumors

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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. Prior results from this study (CTR20160872) showed tislelizumab was generally well tolerated and had antitumor activity in pts with advanced solid tumors; updated data from pts with EC, GC, HCC, and MSI-H/dMMR are presented.

Methods Eligible pts had histologically or cytologically confirmed advanced tumors and progressed from/were intolerable to their last 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 tislelizumab.

Results As of 01 Dec 2018, 83 EC, GC, HCC, or MSI-H/dMMR pts (median age: 57–63 yr) received tislelizumab 200 mg IV Q3W. 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).

	EC (n=26)	GC* (n=24)	HCC (n=18)	MSI-H/dMMR* (n=16)
Remaining on treatment, %	11.5	16.7	38.9	43.8
≥2 prior anticancer regimens, %	84.6	58.3	50.0	68.8
Follow-up, mo (range)	4.8 (1.5-19.2)	5.5 (0.8-18.2)	7.8 (3.0-16.7)	10.6 (2.1-17.4)
Confirmed ORR, % (95% CI)	7.7 (0.9-25.1)	16.7 (4.7-37.4)	16.7 (3.6-41.4)	18.8 (4.0-45.6)
Median PFS, mo (95% CI)	2.2 (2.0-4.2)	2.2 (2.0-4.0)	4.0 (2.1-NR)	6.1 (2.0-NR)
Median OS, mo (95% CI)	4.8 (3.6-8.4)	4.7 (2.4-NR)	NR	NR
OS probability at 1 yr (95% CI)	0.2 (0.1-0.4)	0.4 (0.2-0.6)	0.6 (0.4-0.8)	0.7 (0.4-0.8)

*1 pt had MSI-H/dMMR GC

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