Tislelizumab in Combination With Chemotherapy in Chinese Patients With Advanced Gastric Or Gastroesophageal Junction (G/GEJ) Cancer: Results From One Cohort of an Ongoing Phase 2 Study

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Introduction Tislelizumab, a humanized IgG4 mAb with high affinity and specificity for PD-1, was specifically engineered to minimize FcγR binding on macrophages, thereby abrogating antibody-dependent phagocytosis, a potential mechanism of T-cell clearance and resistance to anti-PD-1 therapy. This phase 2 study (NCT03469557) evaluated safety, tolerability, and antitumor activity of first-line tislelizumab plus chemotherapy in Chinese pts with advanced G/GEJ or esophageal cancer; data from the G/GEJ cohort are presented here.

Methods Adult pts with histologically or cytologically confirmed HER2 negative G/GEJ were treated with tislelizumab (200 mg IV Q3W) + oxaliplatin (130 mg/m² IV Q3W for up to 6 cycles) + capecitabine (1000 mg/m² BID, Days 1–14 Q3W). AEs were assessed per CTCAE v4.03; tumor responses were assessed every 9 wks.

Results As of 13 June 2018, 15 G/GEJ pts (median age, 59 yr; M/F, 11/4) were enrolled; median treatment duration was 171 days (range 21–251). AEs in >2 pts considered related to chemotherapy and/or tislelizumab are detailed in the Table. No fatal AEs occurred. Three pts discontinued treatment due to ascites or increased ALT, AST, or total bilirubin. With a median follow up of 181 days, 46.7% (n=7) had confirmed PR, 20% (n=3) had SD, 13.3% (n=2) with non-target disease only at baseline had non-CR/non-PD, 6.7% (n=1) had PD, and 13.3% (n=2) did not have evaluable disease. ORR and DCR were 46.7% (n=7/15) and 80% (n=12/15), respectively.

Conclusion First-line tislelizumab plus chemotherapy was generally well tolerated and antitumor activity was observed in pts with advanced G/GEJ cancer.

Event (SOC/PT)	All Grades (N=15)	Grades 3–4 (N=15)
Asthenia	8 (53.3)	0
Increased AST	7 (46.7)	1 (6.7)
Nausea	7 (46.7)	0
Vomiting	6 (40.0)	1 (6.7)
Increased ALT	6 (40.0)	1 (6.7)
Increased blood bilirubin	5 (33.3)	1 (6.7)
Decreased platelet count	5 (33.3)	0
Thrombocytopenia	5 (33.3)	1 (6.7)
Decreased appetite	5 (33.3)	1 (6.7)
Diarrhea	4 (26.7)	1 (6.7)
Anemia	4 (26.7)	0
Decreased neutrophil count	3 (20.0)	1 (6.7)
Decreased WBC count	3 (20.0)	0
Hypoesthesia	3 (20.0)	0
Leukopenia	3 (20.0)	0
Neutropenia	3 (20.0)	0