

Tislelizumab in Combination With Chemotherapy for the Treatment of Chinese Patients (pts) With Esophageal Squamous Cell Carcinoma (ESCC): Results From One Cohort of an Ongoing Phase 2 Study.

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Background: Tislelizumab, a humanized IgG4 mAb with high affinity and specificity for PD-1, is specifically engineered to minimize binding to FcγR 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) assessed the safety and tolerability of tislelizumab combined with chemotherapy as first-line therapy in pts with gastric cancer and ESCC; the results of the ESCC cohort are presented here. **Methods:** Chinese pts with inoperable, locally advanced ESCC were treated with tislelizumab (200 mg IV Q3W), cisplatin (80 mg/m² IV Q3W for up to 6 six cycles), and fluorouracil (800 mg/m²/d, Days 1-5 IV Q3W for up to 6 six cycles). Safety/tolerability of the combination regimen was assessed by monitoring adverse events (AEs) per NCI-CTCAE v4.03 criteria. **Results:** As of 13 June 2018, 15 pts (median age, 61 yrs; male/female, 14/1) were enrolled. The median treatment duration was 108 days (range 21-201). The mean (Q1, Q3) dose intensity was 0.92 (0.91, 0.97) for tislelizumab, 0.91 (0.90, 0.98) for cisplatin, and 0.78 (0.72, 0.97) for 5-FU. Among 15 pts, AEs occurring in > 2 pts reported to be related to chemotherapy and/or tislelizumab are detailed in the Table. One pt experienced grade 5 hepatic dysfunction (possibly from progressive disease and underlying hepatitis) which was possibly related to study treatment, according to the investigator. Four pts discontinued study treatment due to AEs (grade 3 tracheal fistula, grade 3 lung infection, grade 2 pneumonitis, and grade 3 increase in aspartate aminotransferase). The antitumor activity data remain unmaturing and may be updated later. **Conclusions:** Tislelizumab combined with chemotherapy was generally well tolerated in pts with advanced ESCC.

	All	Grade ≥3
Decreased appetite	9	1

Nausea	8	0
Anemia	6	1
White blood cell count decreased	6	1
Vomiting	5	3
Neutrophil count decreased	5	1
Hypoalbuminemia	4	0
Thrombocytopenia	4	1
Asthenia	4	1
Data presented as n		