**Tislelizumab, an Anti-PD-1 Antibody, in Patients With Urothelial Carcinoma (UC): Results From an Ongoing Phase 1/2 Study**

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**Background** Tislelizumab, a humanized IgG4 mAb with high affinity and specificity for PD-1, was engineered to minimize binding to FcγR on macrophages, thus abrogating antibody-dependent phagocytosis, a potential mechanism of T-cell clearance and resistance to anti-PD-1 therapy. Previous reports from this first-in-human study (NCT02407990), and other early phase studies, suggest tislelizumab was generally well tolerated and had antitumor activity in pts with advanced solid tumors.

**Methods** Patients with UC received tislelizumab at doses of 2, 5, or 10 mg/kg Q2W or Q3W, and 200 mg Q3W. Tumor cell (TC) and immune cell (IC) PD-L1 expression were retrospectively assessed with the VENTANA PD-L1 (SP263) assay. Adverse events (AEs) were assessed per NCI-CTCAE 4.03 and tumor assessments were performed every 9 wks using RECIST v1.1.

**Results** A total of 17 pts with UC (median age, 71 yr [range 39–79]) received tislelizumab, the majority of which received 5 mg/kg Q3W (n=11). All pts were Caucasian and 14 were male; median number of prior systemic anticancer therapies was 1 (range 0–4). Treatment-related AEs (TRAEs) occurring in ≥3 pts included fatigue (n=5), infusion-related reaction (n=3), and rash (n=3). Grade ≥3 TRAEs were fatigue, hyperglycemia, and type 1 diabetes mellitus (T1DM; n=1 each). Three pts experienced serious TRAEs (infusion-related reaction [n=1], hyperglycemia and T1DM [n=1], and pneumonitis [n=1]). As of 27 Apr 2018, median duration of follow up was 8.8 mo (range 0.9–29.1) and 2 pts remained on treatment. All pts were evaluable for response. Confirmed CR (n=1) and PR (n=4) were observed; SD was achieved in 3 pts. ORR and DCR were 29% (95% CI 10.3, 55.9) and 47% (95% CI 22.9, 72.1), respectively. Sixteen samples were available for PD-L1 evaluation. Responses were observed in 4 (n=1 CR; n=3 PR) of 10 pts with PD-L1$^+$ tumors (defined as ≥25% TC or IC expressing PD-L1 by IHC), while 1 (PR) in 6 pts with PD-L1$^-$ tumors responded.

**Conclusions** Tislelizumab was generally well tolerated in pts with UC and responses were observed in both PD-L1$^+$ and PD-L1$^-$ diseases. Tislelizumab is currently being investigated in China as monotherapy for pts with PD-L1$^+$ UC (CTR20170071).