Tislelizumab in Chinese Patients With Melanoma, Urothelial Carcinoma (UC), and Renal Cell Carcinoma (RCC)

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Background Tislelizumab is an investigational monoclonal antibody with high affinity and specificity for PD-1 that 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 demonstrated preliminary antitumor activity in patients (pts) with advanced solid tumors; updated data from pts with melanoma, UC, and RCC 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 using RECIST v1.1, survival was estimated using Kaplan-Meier methodology, 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, 77 pts with melanoma (n=34), UC (n=22), or RCC (n=21) were treated with tislelizumab 200 mg IV Q3W. Median age was 54, 62, and 53 yr for pts with melanoma, UC, and RCC, respectively. Across the entire 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).

	Melanoma (n=34)	UC (n=22)	RCC (n=21)
Remaining on treatment, n (%)	7 (20.6)	8 (36.4)	6 (28.6)
≥2 prior anticancer regimens, n (%)	18 (52.9)	14 (63.6)	14 (66.7)
Follow-up, mo (range)	8.2 (1.0-18.0)	4.2 (0.9-21.9)	15.5 (2.9-18.0)
Confirmed ORR, % (95% CI)	14.7 (5.0-31.1)	13.6 (2.9-34.9)	9.5 (1.2-30.4)
Median PFS, mo (95% CI)	2.3 (2.1-6.1)	2.1 (2.0-4.3)	4.1 (2.1-10.4)
Median OS, mo (95% CI)	11.3 (6.8-18.0)	4.3 (2.1-NR)	NR
Probability of OS at 1 yr (95% CI)	0.4 (0.2-0.6)	0.3 (0.1-0.6)	0.7 (0.5-0.9)

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