**Preliminary Results With Tislelizumab, an Investigational Anti-PD-1 Antibody, in Chinese Patients With Nasopharyngeal Cancer (NPC)**

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**Background** Epidemiology of NPC is characterized by a unique geographic distribution, with China having one of the highest incidence rates of NPC worldwide. Tislelizumab is an investigational monoclonal antibody with high affinity and specificity for PD-1. Tislelizumab 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. Previous reports from this phase 1/2 study (CTR20160872) have shown that single-agent tislelizumab was generally well tolerated and demonstrated preliminary antitumor activity in Chinese patients (pts) with advanced solid tumors. In the dose-verification part of this study, the recommended dose was established as 200 mg IV Q3W. Here we present preliminary results from the NPC cohort of this study.

**Methods** Chinese pts with advanced or metastatic, histologically or cytologically confirmed WHO type II-III NPC were enrolled in the indication-expansion phase of this study. Enrolled pts received tislelizumab 200 mg IV Q3W until unacceptable toxicity, consent withdrawal, or no evidence of continued clinical benefit. Antitumor activity (per RECIST v1.1) and safety/tolerability (per NCI-CTCAE v4.03) were assessed.

**Results** As of 11 May 2018, 20 NPC pts (median age 49 yr [range 35–61]) were enrolled. Most pts were male (85%) and non-smokers (65%). All pts received prior radiotherapy; 19 pts (95%) received ≥1 line of systemic treatment and the median number of prior lines of systemic treatment was 2 (range 0–10). At the cut-off date, 15 pts remain on treatment and the median study follow-up was 5.5 mo (range 0.46–9.0). Of 15 response-evaluable pts, 3 achieved a confirmed partial response (PR) and 9 achieved stable disease; 1 patient had an unconfirmed PR. Seven patients experienced ≥1 treatment-related AE (TRAE); hypothyroidism (n=3) was the only TRAE that occurred in ≥2 pts. No grade ≥3 TRAEs or serious AEs were reported. Furthermore, no AEs led to either treatment interruption or discontinuation.

**Conclusions** Tislelizumab was generally well tolerated and demonstrated antitumor activity in previously treated pts with advanced NPC.