AdvanTIG-202: Phase 2 Randomized, Multicenter, Open-Label Study of Tislelizumab (TIS) With or Without Ociperlimab (OCI) in Patients (pts) With Previously Treated Recurrent/Metastatic (R/M) Cervical Cancer (CC)

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Background: Pts with R/M CC have poor prognoses with high unmet clinical needs and few treatment (tx) options. Dual targeting of solid tumors with anti-T-cell immunoreceptor with immunoglobulin and immunoreceptor tyrosine-based inhibitory motif domains (TIGIT) and anti-PD-1 mAbs enhances antitumor activity in preclinical studies and clinical studies of other tumors. AdvanTIG-202 (NCT04693234) is investigating the efficacy and safety of TIS (anti-PD-1 mAb) ± OCI (humanized Fc-intact IgG1 anti-TIGIT mAb) in pts with R/M CC. Primary analysis results are reported here.

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Methods: Eligible pts with R/M CC had received ≥1 line of chemotherapy and were not amenable to curative tx. In Stage 1, 80 pts were randomized (1:1) to receive 200 mg TIS IV Q3W + 900 mg OCI IV Q3W (Cohort [C]1) or TIS monotherapy (C2) until disease progression, unacceptable toxicity, or withdrawal of consent. In Stage 2, C1 enrolled 98 additional pts. Primary endpoint: ORR per RECIST v1.1 by IRC for C1. Secondary endpoints: DoR, PFS, OS, and safety.

Results: As of June 16, 2022, 138 pts were enrolled and treated in C1 (median age 53.0 y); median study follow-up: 7.4 mo. In the safety analysis set, the ORR was 22.5%, with 13 complete responses (CR; **Table**); 76.8% had a durable response of ≥6 mo. ORR was 26.2% in pts with PD-L1+ tumors (PD-L1 score ≥5%), with 10 CRs. Both analysis sets showed significant improvement in ORR vs historical control ORR of 15% in pts treated with anti-PD-1 therapy (P<0.05). Around 67% of pts experienced ≥1 tx-related adverse event (TRAE). Only 13% of pts experienced ≥grade 3 TRAEs; the most frequently reported were anemia (2%) and rash (1%). With limited enrollment in C2 (n=40), the ORR was 32.5%.

Conclusions: OCI + TIS showed promising antitumor activity and durable responses, regardless of PD-L1 expression, and was well tolerated in pts with previously treated R/M CC.

Table

Cohort 1	**Safety analysis set**[a] (n=138)	**PD-L1 +** (n=84)
ORR, % (95% CI)	22.5 (15.8, 30.3)	26.2 (17.2, 36.9)
	n (%)	
Complete response	13 (9.4)	10 (11.9)
Partial response	18 (13.0)	12 (14.3)
Stable disease	56 (40.6)	34 (40.5)
Progressive disease	39 (28.3)	20 (23.8)
Not determined	12 (8.7)	8 (9.5)
mDoR, mo 95% CI	NE (5.6, NE)	NE (5.6, NE)
mPFS, mo 95% CI	3.5 (2.6, 4.9)	4.2 (2.7, 6.9)
mOS, mo 95% CI	9.0 (8.1, 10.4)	10.4 (8.1, NE)

Data cutoff: June 16, 2022. Efficacy assessed by IRC.
[a]Pts who received ≥1 dose of any study drug.
DoR, duration of response; IRC, independent review committee; m, median; mo, months; NE, not estimable; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.