AdvanTIG-202: A Phase 2 study investigating anti-T cell immunoglobulin and ITIM domain monoclonal antibody ociperlimab plus tislelizumab in patients with previously treated recurrent or metastatic cervical cancer

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Abstract Body:

Objective:

Women with recurrent/metastatic cervical cancer represent a poor prognostic group with high unmet clinical needs. T cell immunoglobulin and immunoreceptor tyrosine-based inhibitory motif domain (TIGIT) is a co-inhibitory, immune checkpoint receptor expressed on immune cells and upregulated on T-cells and natural killer cells in multiple solid tumors, inhibiting anticancer immune responses. Ociperlimab (BGB-A1217) is a novel, humanized, monoclonal antibody that binds TIGIT with high specificity and affinity, blocking the interaction with its ligands on tumor cells. Tislelizumab is an anti-PD-1 antibody engineered to minimize binding to FcγR on macrophages to abrogate antibody-dependent phagocytosis, a mechanism of T-cell clearance and potential resistance to anti-PD-1 therapy. Preclinical and clinical studies suggest that dual targeting with anti-TIGIT and anti-PD-1 antibodies produces synergistic immune cell activation and enhanced antitumor activity.

Methods:

AdvanTIG-202 is a Phase 2, randomized, multicenter, open-label study (NCT04693234). Approximately 167 patients with cervical squamous cell or adenosquamous carcinoma or adenocarcinoma, recruited from 100 centers, whose disease progressed on or after ≥ 1 prior line of chemotherapy for recurrent/metastatic disease will be included in this 2-Part study. In Part 1, approximately 80 patients will be randomized (1:1) to either ociperlimab 900 mg IV in combination with tislelizumab 200 mg IV every 3 weeks (Q3W) (Cohort 1), or tislelizumab monotherapy 200 mg IV Q3W (Cohort 2), until disease progression, unacceptable toxicity, or withdrawal of consent. In Part 2, Cohort 1 will be expanded by approximately 87 additional patients whose tumors are evaluable for PD-L1 expression. The primary endpoint is objective response rate (ORR) (RECIST v1.1) assessed by Independent Review Committee (IRC) in Cohort 1. Secondary endpoints are investigator-assessed ORR in Cohort 1, IRC-assessed and investigator-assessed ORR in Cohort 2, IRC-assessed and investigator-assessed duration of response, progression-free survival, time to response, disease control rate, clinical benefit rate, and overall survival, cancer-specific health-related quality of life (HRQoL), safety, pharmacokinetics and immunogenicity in Cohorts 1 and 2. Exploratory endpoints are generic HRQoL and the association of biomarkers with patient prognosis, response or resistance.