AdvanTIG-206: Anti-TIGIT monoclonal antibody (mAb) ociperlimab (BGB-A1217; OCI) plus anti-programmed cell death protein-1 (PD-1) mAb tislelizumab (TIS) plus BAT1706 vs TIS plus BAT1706 as first-line treatment for advanced hepatocellular carcinoma (HCC)

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Abstract Body:

Background*: Treatment with PD-1/programmed death-ligand 1 (PD-L1) inhibitors and anti-angiogenic agents has demonstrated significant survival improvements in patients with untreated HCC. T cell immunoglobulin and immunoreceptor tyrosine-based inhibitory motif domain (TIGIT) is a co-inhibitory immune checkpoint receptor upregulated on T cells and natural killer cells in multiple solid tumors. OCI is a novel, humanized mAb that binds TIGIT with high specificity and affinity, blocking interaction with its ligands on tumor cells. TIS is an anti-PD-1 mAb that has demonstrated clinical activity in patients with previously treated, unresectable HCC (NCT03419897). BAT1706 is a similar biological product to the anti-angiogenic agent bevacizumab. OCI combined with TIS and BAT1706 could further enhance both anti-angiogenic and anti-PD-1 therapies for patients with HCC.

Methods: AdvanTIG-206 is a Phase 2, randomized, open-label clinical study (NCT04948697). Patients aged ≥ 18 years with histologically confirmed advanced HCC that is not amenable to a curative treatment approach are eligible. Patients must have a Child-Pugh A score, ECOG PS ≤ 1, and have received no prior systemic therapy for HCC. Approximately 90 patients will be randomized 2:1 to OCI 900 mg combined with TIS 200 mg plus BAT1706 15 mg/kg (Arm A) or TIS 200 mg plus BAT1706 15 mg/kg (Arm B), all administered intravenously (once every 3 weeks [Q3W]). The primary endpoint is investigator-assessed objective response rate per RECIST v1.1. Radiological assessment of tumor response status will be performed Q6W for the first 48 weeks and Q12W thereafter. Secondary endpoints

include duration of response, time to response, disease control rate, clinical benefit rate, and progression-free survival (all investigator-assessed), overall survival, safety, pharmacokinetics, and immunogenicity. Study enrollment is ongoing.