AdvanTIG-302: Anti-TIGIT monoclonal antibody ociperlimab+tislelizumab in non-small cell lung cancer

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Background: Ociperlimab (OCI, BGB-A1217), a humanized monoclonal antibody, binds T-cell immunoreceptor with immunoglobulin and immunoreceptor tyrosine-based inhibition motif domain (TIGIT) with high affinity/specificity, inducing cytotoxicity. Here, we report design of a trial investigating synergistic antitumor activity of dual anti-TIGIT and anti-PD-1 antibody targeting.

Methods: AdvanTIG-302 is a Phase 3, international, randomized, double-blind study (NCT04746924) investigating OCI+tislelizumab (TIS) vs pembrolizumab (PEM) in adults with PD-L1 selected, previously untreated, locally advanced, unresectable or metastatic non-small cell lung cancer without oncogenic *EGFR* or *ALK* mutation. About 660 pts will be randomized 5:5:2 to IV OCI 900mg+TIS 200mg Q3W, PEM 200mg+placebo Q3W, or TIS 200mg+placebo Q3W. Pts will be treated until disease progression, loss of clinical benefit, or intolerable toxicity. Stratification factors include histology and region. Cross-over is not permitted. Key eligibility criteria include histologically confirmed disease, PD-L1 expression ≥50%, and no prior checkpoint inhibitor therapy.

Results: Dual primary endpoints are progression-free survival by investigator (PFS; RECIST v1.1) and overall survival. Secondary endpoints include PFS (Blinded Independent Review Committee), overall response rate and duration of response, safety and tolerability, and health-related quality of life. Exploratory endpoints include disease control rate, clinical benefit rate and time to response. Biomarkers will be evaluated.

Conclusions: Study recruitment is ongoing.