BGB-HNSCC-201 (NCT05909904): Phase 2, Open-Label, Multi-Arm, Global Study of Tislelizumab (TIS) + Investigational Agents as First-Line (1L) Treatment in Patients (Pts) With Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC)

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Background

HNSCC is the 7th most common cancer worldwide (Sung et al, *CA Cancer J Clin* 2021;71:209–249). Anti-programmed cell death-protein 1 (PD-1) therapy, either alone or in combination with chemotherapy (CT), extended overall survival (OS) vs cetuximab + CT in pts with programmed cell death-ligand 1 (PD-L1)-positive R/M HNSCC in the 1L setting; however, not all pts respond to single-agent anti-PD-1 therapy. Identifying novel agents that synergize with anti-PD-1 therapies by targeting distinct biological pathways may improve efficacy. TIS is an anti-PD-1 monoclonal antibody (mAb) currently approved in China for multiple indications. This Phase 2 study will assess efficacy and safety of TIS in combination with investigational agents targeting the immune-checkpoint inhibitors TIM-3 (BGB-A425) and/or LAG-3 (LBL-007) as 1L treatment in pts with R/M HNSCC.

Trial design

This multicenter (77 sites; 14 countries) study will enroll approximately 160 pts (40 per arm) aged ≥18 years with immunotherapy-naïve, PD-L1 positive (combined positive score [CPS] ≥1) R/M HNSCC of the oropharynx, oral cavity, hypopharynx, or larynx, who are not candidates for local/curative therapy and have ≥1 measurable lesion (per RECIST v 1.1). Pts will be randomized 1:1:1:1 (stratified by PD-L1 CPS: 1–19 vs ≥20) to TIS monotherapy, TIS + BGB-A425, TIS + LBL-007, or TIS + BGB-A425 + LBL-007. TIS 200 mg, BGB-A425, and LBL-007will be administered by separate intravenous infusions once every 3 weeks for up to 2 years, until disease progression, intolerable toxicity, withdrawal of informed consent, or other discontinuation event, whichever occurs first. The primary endpoint is confirmed objective response rate (per investigator; RECIST v1.1). Secondary endpoints include progression-free survival, duration of response, clinical benefit rate, and disease control rate (all per investigator; RECIST v1.1) as well as safety, OS, and immunogenicity to study drugs. Enrollment is ongoing and additional experimental arms may be added in the future.