Phase 1/1b Study Investigating Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Anti-TIGIT Monoclonal Antibody BGB-A1217 in Combination with Anti-PD-1 Monoclonal Antibody Tislelizumab (BGB-A317) in Patients with Unresectable Locally Advanced or Metastatic Solid Tumors

Status: Not yet recruiting

Eligibility Criteria

Sex: All
Age: 18 Years and over
This study is NOT accepting healthy volunteers

Key

Inclusion Criteria:

Phase 1 Key Inclusion Criteria 1. Has Eastern Cooperative Oncology Group (ECOG) Performance Status ≤1. 2. ≥ 1 measurable lesion per RECIST v1.1. 3. Has adequate organ function. 4. phase 1- Patients with histologically or cytologically confirmed advanced, metastatic, unresectable solid tumors who have previously received standard systemic therapy or for which treatment is not available, not tolerated or refused. Phase 1b Key Inclusion Criteria 1. Signed informed consent form (ICF) and able to comply with study requirements. 2. Age ≥18 years (or the legal age of consent) at the time the ICF is signed. 3. Histologically or cytologically confirmed tumor types in the following disease cohorts: Cohort 1: stage IV squamous NSCLC Cohort 2: stage IV non-squamous NSCLC Cohort 3: stage IV squamous or non-squamous NSCLC with PD-L1 positive. Cohort 4: extensive-stage SCLC Cohort 5: stage IIIIB, IIIIC or IV NSCLC Cohort 6: stage IV ESCC Cohort 7: stage IV EAC Cohort 8: recurrent or metastatic HNSCC inurable by local therapies Cohort 9: stage IV G/GEJ adenocarcinoma. 4. ECOG Performance Status ≤ 1. 5. Adequate organ function 6. Willing to use highly effective method of birth control Phase 1 Key

Exclusion Criteria:

1. Active brain or leptomeningeal metastasis. 2. Active autoimmune diseases or history of autoimmune diseases that may relapse. 3. With severe chronic or active infections requiring systemic antibacterial, antifungal or antiviral therapy, including tuberculosis infection, etc. (antiviral therapy is permitted for patients with hepatocellular carcinoma). 4. Concurrent participation in another therapeutic clinical trial. 5. Received prior therapies targeting TIGIT. Phase 1b Key

Exclusion Criteria:

1. Patients with any prior therapy for recurrent/metastatic disease. 2. Non-squamous NSCLC patients with sensitizing epidermal growth factor receptor (EGFR) mutation, anaplastic lymphoma kinase (ALK) fusion, and c-ros oncogene 1 (ROG1) fusion. 3. Gastric cancer patients with squamous or with positive HER2 expression. 4. Prior therapy with any drug specifically targeting T-cell co-stimulation or checkpoint pathways. (anti-PD(L)1 exception for Cohort 5). 5. Active leptomeningeal disease or uncontrolled brain metastasis. 6. Active autoimmune diseases or history of autoimmune diseases that may relapse. 7. With severe chronic or active infections requiring systemic antibacterial, antifungal or antiviral therapy, including tuberculosis infection, etc. (antiviral therapy is permitted for patients with hepatocellular carcinoma). 8. Concurrent participation in another therapeutic clinical study. NOTE: Other protocol defined Inclusion/Exclusion criteria may apply.

Conditions & Interventions

Interventions:

Conditions:
Locally Advanced and Metastatic Solid Tumors

Keywords:
BGB-A1217, Anti-TIGIT antibody, Tislelizumab, anti-PD-1, Clinics and Surgery Center (CSC)

More Information

Description: This is an open-label, multicenter, Phase 1 and Phase 1b study to evaluate the safety and preliminary antitumor activity of BGB-A1217 in combination with tislelizumab in patients with unresectable locally advanced or metastatic solid tumors. The primary endpoint of the Phase 1b portion includes: Overall response rate (ORR), as determined by investigator derived tumor assessments per RECIST v1.1 for each tumor expansion cohort.

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