

Phase I open-label dose escalation trial of BI 3923948 monotherapy and in combination with an anti-PD-1 mAb in patients with advanced, unresectable and/or metastatic solid tumors

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

Inclusion criteria: 1. Measurable disease as defined per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1. 2. Patient has 1 or more accessible lesions (2 or more preferred) 3. Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 4. Life expectancy of at least ≥ 3 months after the start of the treatment according to the investigator's judgement Further inclusion criteria apply. Exclusion criteria: 1. Patients with known primary brain tumors, leptomeningeal disease or untreated brain metastases. Subjects with previously treated brain metastases may participate provided the brain metastases are stable 2. Previous treatment with vesicular stomatitis virus (VSV)-based agents 3. Concomitant medication or condition considered a high risk for complications from injection 4. History of common terminology criteria for adverse events (CTCAE) v5 grade 3 or higher severe hypersensitivity reactions to previous anti-programmed cell death 1 (anti-PD-1)/anti-programmed cell death ligand 1 (PD-L1) monoclonal antibody (mAb) (Arm B only) Further exclusion criteria apply.

Conditions & Interventions

More Information

Description: BI 3923948 is an oncolytic that carries GSDME and IL12 therapeutic cargos, which are expressed during virus replication and drive distinct pathways of cancer cell death. The trial will characterize the safety and tolerability of BI 3923948 by itself and in combination with enzabenlimab in subjects with advanced solid tumors.

Study Contact: Manish Patel - patel069@umn.edu

Principal Investigator: Manish Patel

Phase: PHASE1

IRB Number: STUDY00026921

Thank you for choosing StudyFinder. Please visit <http://studyfinder.umn.edu> to find a Study which is right for you and contact sfinder@umn.edu if you have questions or need assistance.