MT2024-08: Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 mAb in patients with advanced or metastatic solid tumors.

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- confirmed diagnosis of an advanced, and/or metastatic or relapsed/refractory solid tumor that can not be surgically removed - must have exhausted available treatment options or refused established treatment options - restricted from physically strenuous activity but able to walk and carry out work of a light or sedentary nature, e.g., light house work, office work - see link to clinicaltrials.gov for additional Inclusion criteria

Exclusion Criteria:

- major surgery or radiation therapy in the past 4 weeks - active hepatitis B or C infection - severe or serious, acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation (study staff will review) - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:
Cancer
Keywords:
Solid Tumors, Clinics and Surgery Center (CSC)

More Information

Description: This study tests the use of the oncolytic virus BI1831169 (VSV-GP) as an immunotherapy in patients with advanced solid tumors. This trial is the first-in-human trial to test the safety and early efficacy of BI1831169 by itself (Part 1) and in combination with the PD-1 inhibitor ezabenlimab (Part 2).
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Phase: PHASE1
IRB Number: STUDY00019229