

## MT2024-08: Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with ezabenlimab 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 - additional inclusion criteria (study staff will review)

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**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)

### Conditions & Interventions

**Interventions:**

Drug: BI 1831169, Drug: ezabenlimab

**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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**IRB**

**Number:** STUDY00019229

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