

MBRC-101-001 Clinical Trial Information Guide

A Multi-center, Open-label Phase 1/1b Dose Finding, Safety, and Pharmacokinetic Study of MBRC-101, an Anti-EphA5 Monomethyl Auristatin E (MMAE) Antibody Drug Conjugate, in Advanced Refractory Solid Tumors.

MBRC-101 is an antibody-drug conjugate (ADC) that targets EphA5, a cell surface receptor highly-expressed in many cancers. EphA5 offers a potential new mechanism by which precision therapies may be selectively delivered to cancer cells.

This highly targeted, first-in-class therapy provides doctors and patients a new modality for cancer treatment and may reduce side effects compared to conventional chemotherapies.







The ADC is given to a cancer patient. The ADC binds to a specific target on the surface of a cancer cell. The ADC enters the tumor cell and then releases its toxic drug.



The toxic drug disrupts cell function and destroys the cancer cell.

MBRC-101-001 Trial Information

The MBRC-101-001 Phase 1/1b clinical trial is a first-in-human, open-label, dose escalation and dose expansion study to evaluate the safety and tolerability of MBRC-101.



In the U.S., this study will enroll approximately 100 patients.

Patient Profile

Patients with locally advanced, recurrent or metastatic cancers refractory to standard treatment, including non-small cell lung cancer (NSCLC), triple negative breast cancer (TNBC), and other solid tumors are encouraged to visit clinicaltrials.gov (identifier: NCT06014658) to further review patient eligibility criteria.

Outcome Measures

- Safety
- Tolerability
- Pharmacokinetics
- Anti-tumor activity
- Response duration

Phase 1 Safety & Dose Escalation

Phase 1 will identify possible optimal doses and evaluate the safety of MBRC-101 in cancer patients.

Key Eligibility Criteria

- → Recurrent locally advanced or metastatic solid tumors
- → 18 years of age or older
- → Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
- → Availability of a tumor tissue sample for EphA5 testing
- → Evaluable or measurable disease according to Response Evaluation Criteria In Solid Tumors [RECIST] v1.1
- Select prior ADC therapy is allowed
- → Adequate hematologic, kidney, and liver function as measured by blood tests

Dose Escalation Design

- Modified Toxicity Probability Interval (m-TPI) design with at least 4 escalating dose levels of MBRC-101
- MBRC-101 will be administered intravenously every 3-weeks
- Approximately 40 patients will be enrolled



- x Prior MMAE-based ADC therapy (Phase 1b only)
- × Major surgery within the past 28 days
- Active opthalmological disease
 X The use of certain medications that may
 - interfere with the metabolism of MBRC-101



Phase 1b will evaluate the safety and preliminary clinical activity of MBRC-101 at potential optimal doses in cancer patients using the doses identified in Phase 1.

Dose Expansion Design (each Cohort will enroll approximately 20 patients)



About MBrace Therapeutics

MBrace Therapeutics, Inc strives to offer new and more effective treatment options for patients. We are among a few ADC research companies identifying novel targets for cancer drugs. The MBrace founders have developed SPARTA, a proprietary drug target discovery platform, to develop first-in-class ADC therapeutics. SPARTA utilizes robust antibody and drug target selection that goes beyond in vitro screening. This innovative technology uniquely combines discovery of new drug candidates with innovative manufacturing techniques. For additional information, please visit MBrace's website at http://www.mbracetrx.com.

For more information about the MBRC-101-001 clinical trial, and to review patient eligibility criteria, visit clinicaltrial.gov (identifier: NCT06014658).