Multicenter Study to Assess the Efficacy and Safety of LB-102 in the Treatment of Adult Patients With BP1MDE.

NCT07494305

Status	RECRUITING
Phase	Phase 2
Sponsor	LB Pharmaceuticals Inc.
Enrollment	320 participants

Key Eligibility Criteria

Inclusion (10)

- Sign IRB approved ICF, Stable living environment
- Diagnosis of Bipolar1 disorder defined by criteria in the DSM 5 and currently experiencing a MDE without psychotic or mixed features, and supported by the SCID 5 CT
- Currently experiencing an MDE that began at least 4 weeks but no more than 18 months prior to randomization
- Currently treated in an out-patient environment
- MADRS 10 total score e24 at both Screening and Baseline with a difference of \<20% in scores between visits.

... and 5 more (see full listing online)

Exclusion (21)

- Sexually active woman of childbearing potential and male who are not practicing 2 different methods of birth control or woman who is currently breast feeding
- History of non-response to 2 adequate medication trials for depressive symptoms
- Improvement of e20% in MADRS 10 total score between the screening and baseline assessments
- Have bipolar disorder with mixed features or considered as rapid cyclers
- Plan to initiate formal cognitive or behavioral therapy, systematic psychotherapy during the study, or plan to initiate such therapy during the study

... and 16 more (see full listing online)

Locations (2 total)

Cenexel Hollywood Florida, Hollywood, Florida, United States
Cenexel Decatur GA, Decatur, Georgia, United States