Multicenter Study of Lumateperone for the Treatment of Bipolar Depression in Pediatric Patients

Status: RECRUITING

Eligibility Criteria

Age: 10 years to 17 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Able to provide consent as follows: * The Legally Authorized Representative (LAR) must provide written, informed consent. * The patient must provide written assent; 2. Male or female patients 10 to 17 years of age, inclusive; 3. Have a Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision (DSM-5-TR) primary diagnosis of bipolar I or bipolar II disorder with a current MDE without psychosis as confirmed by Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL); 4. Subject has a lifetime history of at least one manic or hypomanic episode. 5. Subject's current major depressive episode is ≥ 4 weeks and less than 12 months in duration; 6. CDRS-R total score ≥ 45 with ≥ 5 on Item 11 (depressed feelings) at Screening and Baseline; 7. Young Mania Rating Scale (YMRS) score ≤ 15 (with YMRS Item 1 \[elevated mood\] score ≤ 2) at Screening and Baseline.

Exclusion Criteria:

1. Has a primary psychiatric diagnosis other than bipolar I or bipolar II disorder. Exception includes: * Attention deficit hyperactivity disorder (ADHD). If a subject is taking medications for ADHD, they must have been on a stable treatment regimen of these medication(s) for 30 days prior to screening and the treatment regimen is expected to remain stable throughout the study. 2. Intellectual disability based on Investigator opinion and DSM-5 criteria 3. Patient has been hospitalized for a bipolar manic episode within the 30 days prior to randomization; 4. Demonstrates a ≥ 25% decrease (improvement) in the CDRS-R total score between Screening and Baseline visits, or the CDRS-R is below 45 at Baseline; 5. In the opinion of the Investigator, the patient has a significant risk for suicidal behavior during his/her participation in the study or 1. At Screening, the patient scores "yes" on Suicidal Ideation Items 3, 4, or 5 of the Columbia-Suicide Severity Rating Scale (C-SSRS) within 6 months prior to Screening or, at Baseline, the patient scores "yes" on Suicidal Ideation Items 3, 4, or 5 since the Screening Visit; 2. At Screening, the patient has had 1 or more suicidal attempts within the 2 years prior to Screening; or 3. At Screening or Baseline, scores \> 3 on Item 13 (suicidal ideation) on the CDRS-R; or 4. The patient is considered to be an imminent danger to him/herself or others.

Conditions & Interventions

Interventions:
DRUG: Lumateperone, DRUG: Placebo
Conditions:
Bipolar Depression

More Information

Contact(s): ITI Clinical Trials - ITCIClinicalTrials@itci-inc.com
Principal Investigator:
IRB
Number:
System ID: NCT06372964
