Safety and Tolerability Trial of Lumateperone in Pediatric Patients With Schizophrenia, Bipolar Disorder or Autism Spectrum Disorder

Status: RECRUITING

Eligibility Criteria

Age: 5 years to 17 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Able to provide consent as follows: * The patient's legally authorized representative (LAR) (eg, parent or guardian) must provide written, informed consent; * The patient must provide written assent to study enrollment; * Male or female patients aged 13 to 17 years (inclusive) with schizophrenia; male or female patients aged 10 to 17 years (inclusive) with bipolar I or II disorder; or male or female patients aged 5 to 17 years (inclusive) with autism spectrum disorder; * Meet Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision (DSM-5-TR) primary diagnosis of schizophrenia, bipolar I or II disorder, or autism spectrum disorder as confirmed by Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL). * Is currently an outpatient and is anticipated to maintain outpatient status for the duration of the study. Rollover Patients entering from the lead-in study must have safely completed the lead-in study, in the opinion of the Investigator.

Exclusion Criteria:

* Has a primary psychiatric diagnosis other than schizophrenia, bipolar I or bipolar II disorder or autism spectrum disorder. Schizophrenia with catatonia, or bipolar disorder with psychotic features are not allowed. Exceptions include: * ADHD: If a subject is taking psychostimulant(s) for ADHD, they must have been on a stable treatment regimen of these medication(s) for 30 days prior to Screening. The treatment regimen should remain stable throughout the study. This must be confirmed by the Investigator and noted in the source records. * For ASD patients only, based on Investigator opinion and DSM-5 criteria, mild or moderate intellectual disability is allowed. Severe or profound intellectual disability is exclusionary. * In the opinion of the Investigator, the patient has a significant risk for suicidal behavior during their participation in the study or * 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; * At Screening, the patient has had 1 or more suicidal attempts within the 2 years prior to Screening; or * At Screening or Baseline, scores \> 3 on Item 13 (suicidal ideation) of the CDRS-R (for bipolar disorder patients only); or * The patient is considered to be an imminent danger to him/herself or others.

Conditions & Interventions

Interventions:
DRUG: Lumateperone
Conditions:
Schizophrenia, Bipolar Disorder, Autism Spectrum Disorder
Keywords:
Pediatric

More Information

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