Multicenter Study of Lumateperone for the Treatment of Irritability Associated With Autism Spectrum Disorder (ASD) in Pediatric Patients

Status: RECRUITING

Eligibility Criteria

Age: 5 years to 17 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. All patients must have a legally authorized representative LAR (eg, parent or legal guardian) who is willing and able to be responsible for the safety and well-being of the patient, provide information about the patient's condition, and accompany the patient to study visits. 2. Able to provide consent as follows: 1. The patient's LAR must provide written, informed consent. 2. When developmentally appropriate based on Investigator judgment, the patient should provide written assent. 3. Male or female patients 5 to 17 years of age. Currently, only patients aged 13 to 17 years will be eligible for enrollment. 4. Meet Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision (DSM-5-TR) primary diagnosis of ASD as confirmed by the Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL); 5. ABC-I subscale score of \>18 at Screening and Baseline; 6. CGI-S score \> 4 with respect to irritability associated with ASD at Screening and Baseline.

Exclusion Criteria:

1. Has a primary psychiatric diagnosis other than ASD. Exceptions include: 1. Attention Deficit Hyperactivity Disorder (ADHD). If a patient is taking medication(s) for ADHD, they must be 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. This must be confirmed by the Investigator and noted in the source records. 2. Mild and moderate intellectual disability based on Investigator judgment and DSM-5 criteria (severe and profound intellectual disability are excluded). 2. History or current diagnosis of Rett syndrome or Fragile X syndrome; 3. In the opinion of the Investigator, the patient has a significant risk for suicidal behavior during their 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 (CSSRS) 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. The patient is considered to be an imminent danger to themselves or others.

Conditions & Interventions

Interventions:
DRUG: Lumateperone high dose, DRUG: Lumateperone low dose, DRUG: Placebo
Conditions:
Irritability Associated With Autism Spectrum Disorder

More Information

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