

ML-004 in Adolescents and Adults With Autism Spectrum Disorders (ASD)

Status: RECRUITING

Eligibility Criteria

Age: 12 years to 45 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Age 12 to 45 at screening * Has a designated care/study partner who can reliably report on symptoms * Has a diagnosis of Autism Spectrum Disorder (ASD) * Has a body mass index (BMI) 18 through 34 kg/m², inclusive * Full scale IQ (or equivalent) ≥55 score, with adequate verbal fluency, as determined by the Principal Investigator. * Psychoactive medications and adjunctive therapies are stable for 4 weeks prior to screening * Must be able to swallow study medication

Exclusion Criteria:

* Has Rett syndrome or Child Disintegrative Disorder * Has participated in any other study and received any other investigational medication (other than COVID-19 vaccination) or device within 60 days prior to screening * History of epilepsy without current adequate control, or any seizure in the 6 months preceding screening * History of suicidal ideation or behavior in the past 12 months, or a positive response to C-SSRS questions 4 and/or 5 * Systolic blood pressure ≥140 mmHg (if adult) or >135 mmHg (if adolescent), or diastolic blood pressure ≥90 (if adult) or >85 mmHg (if adolescent), or a clinical history of uncontrolled or severe hypertension * If female, is pregnant or lactating

Conditions & Interventions

Interventions:

DRUG: ML-004 (IR)/(ER) tablet, DRUG: ML-004 Placebo

Conditions:

Autism Spectrum Disorder

Keywords:

ASD, Autism, Autism Spectrum Disorder, Social Communication

More Information

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Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT05081245

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