A Phase II Multicenter, Randomized, Double-Blind, 12-Week Treatment, 3-Arm, Parallel-Group, Placebo-Controlled Study to Investigate the Efficacy, Safety and Tolerability of RO7017773 in Participants Aged 15 to 45 Years with Autism Spectrum Disorder (ASD)

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 15 Years to 45 Years old
This study is NOT accepting healthy volunteers
Inclusion Criteria

• Male and female participants with Autism Spectrum Disorder according to Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)

• Wechsler Abbreviated Scale of Intelligence (WASI-II) >/= 50 at screening or within the last 12 months prior to screening

• ASD or Autism diagnosis confirmed by Autism Diagnostic Observation Schedule (ADOS-2)

• Body mass index within the range of 18.5 to 40 kg/m2

• Female Participants: is eligible if she is not pregnant, not breastfeeding, and women of childbearing potential (WOCBP), who agree to remain abstinent or use contraceptive methods that result in a failure rate of < 1% per year during the treatment period and for at least 28 days after the last dose of study drug

• Language, hearing, and vision compatible with the study measurements as judged by the Investigator

• Allowed existing treatment regimens should be stable for 8 weeks prior to screening. Investigator expects stability of these treatments and behavioral interventions for the duration of the study

• In the Investigator's opinion, able to participate and deemed appropriate for participation in the study, capable of following the study SoA and able to comply with the study restrictions

• In the Investigator's opinion, participation in the study or discontinuation of prohibited medication will not pose undue risks Exclusion Criteria Neurologic/Psychiatric Conditions:

• Non-verbal individuals

• Presence of chromosome 15q11.2 q13.1 duplication syndrome (Dup15q syndrome) genetically defined ASD per genetic results available prior to screening or known "syndromic" forms of ASD (e.g., fragile X syndrome, Prader Willi syndrome, Rett's syndrome, or tuberous sclerosis).

• Medical history of alcohol and/or substance abuse/dependence in the last 12 months or positive test for drugs of abuse at screening

• Initiation of a major change in psychosocial intervention within 6 weeks prior to screening. Minor changes in ongoing treatment are not considered major changes

• Clinically significant psychiatric and/or neurological disorder that may interfere with the safety or efficacy endpoints

• Risk of suicidal behavior in the opinion of a certified clinician or as evidenced by a "yes" to questions 4 and/or 5 of Columbia-Suicide-Severity Rating Scale (C-SSRS) taken at screening and baseline with respect to the last 12 months, or any suicide attempt in the past 5 years

• Unstable epilepsy/seizure disorder within the past 6 months or changes in anticonvulsive therapy within the last 6 months Other Conditions:

• Medical history of malignancy if not considered cured or if occurred within the last 3 years with the exception of fully excised non-melanoma skin cancers or in-situ carcinoma of the cervix that has been successfully treated

• Concomitant disease, condition or treatment which would either interfere with the conduct of the study or pose an unacceptable risk to the participant in the opinion of the Investigator Prior/Concomitant Therapy

• Use of prohibited medications or herbal remedies within 6 weeks or 5 half-lives (t1/2) prior to randomization Prior/Concurrent Clinical Study Experience:

• Donation or loss of blood over 500 mL in adults and 250 mL in adolescents within 3 months prior to randomization

• Participation in an investigational drug study within 1 month or 5 times the t1/2 of the investigational molecule prior to randomization or participation in a study testing an investigational medical device within 1 month prior to randomization or if the device is still active Diagnostic Assessments

• Confirmed clinically significant abnormality in hematological, chemistry or coagulation laboratory parameters

• Positive test result at screening for hepatitis B surface antigen, hepatitis C virus (HCV, untreated), or human immunodeficiency virus (HIV)-1 and -2. HCV participants who have been successfully treated and who test negative for HCV RNA, may be considered eligible for entry into the study Other Exculsions:

• Uncorrected hypokalemia or hypomagnesaemia

Conditions & Interventions

Interventions:
Drug: Placebo, Drug: RO7017773
Conditions:
Autism Spectrum Disorder (ASD)

More Information

Description: Phase II Multicenter, Randomized, Double-Blind, 12-Week Treatment, 3-Arm, Parallel-Group, Placebo-Controlled Study
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Phase: Phase 2
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