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Autism Trial with RG7314

Summary

- **Study director:** Robert Hendren, DO
- **Sponsor:** Hoffman-La Roche
- **Recruiting?:** Yes
- **Official study title:** A Multi-center, Randomized, Double-blind, 12-week, Parallel Group, Placebo-controlled Proof of Concept Study to Investigate the Efficacy and Safety of RG7314 in Individuals With Autism Spectrum Disorders (ASD)
- **ClinicalTrials.gov identifier:** NCT01793441
- **Conditions studied:** Autistic disorder
- **Intervention:** RG7314
- **Phase:** Phase II
- **Purpose:** To investigate the efficacy and safety of RG7314 in adult patients with autism spectrum disorders. In stage I of the study, patients will be randomized to receive daily oral doses of 1.5 mg RG7314 or placebo for 12 weeks. After an independent safety review, the study may proceed to stage II. In stage II of the study, additional patients will be randomized to receive daily oral doses of 1.5mg, 4 mg of RG7314 or placebo for 12 weeks. After an interim efficacy and safety analysis, additional patients may be randomized to receive daily oral doses of 1.5 mg, 4 mg of RG7314 or placebo for 12 weeks.

Eligibility

- **Inclusion criteria:**
  - Patients with a diagnosis of autistic disorder as defined by DSM-IV, confirmed by the team and supported with the Autistic Diagnostic Observation Schedule (ADOS)
  - Male adults, 18 to 45 years of age
  - IQ over 70 (Wechsler Adult Intelligence Scale-Full scale)
  - Body mass index (BMI) 18 to 35 kg/m2 inclusive
  - Aberrant Behavior Checklist (ABC) — Irritability subscale score less than or equal to 13
- **Exclusion criteria:**
  - Positive urine test for drugs of abuse
  - Alcohol and/or substance abuse/dependence during the last 12 months
  - Positive for hepatitis B, hepatitis C or HIV infection
  - Clinically relevant cardiovascular, renal, hepatic or hematologic disease or disorder
  - Active inflammatory pulmonary disease
  - History of epilepsy/seizure disorder (except for simple febrile seizures)
  - Initiation of new or major change in psychosocial intervention within 4 weeks prior to randomization
  - Treatment with any investigational agent within 90 days prior to screening
  - History of hypersensitivity or allergic reactions

What is involved?

- **Testing:** Behavioral assessments, cognitive testing, parent questionnaires, physical examinations, EKGs, blood and urine specimen collection, and vital signs
- **Frequency of visits:** Subject will come to UCSF clinic for up to 7 visits in 18 weeks. The other 10 visits can be done at subject's home with Symphony nurse. The study will last up to 24 weeks (screening period can last up to 5 weeks, treatment period will last 12 weeks, and follow up period up to 7 weeks after the last dose of study medication—hence total of 24 weeks in the study is possible).
- **Materials needed prior to evaluation:** Past medical records
- **Costs:** No costs will be charged for any of the study procedures. We will provide $40 for each visit, to help with costs of transportation and parking.

Contact information

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