ForPatients
by Roche

Autism Spectrum Disorder

A Study of RG7314 to Investigate Efficacy and Safety in Individuals With Autism Spectrum Disorders (VANILLA)

A Study of RG7314 to Investigate Efficacy and Safety in Individuals With Autism Spectrum Disorders (ASD)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT01793441 2012-005597-55 BP28420

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This multi-center, randomized, double-blind, parallel group, placebo-controlled, proof of concept study will investigate the efficacy and safety of RG7314 in adult participants with ASD. In Stage I of the study, participants will be randomized in 2:1 to receive daily oral doses of 1.5 milligrams (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 participants will be randomized in 2:1 to receive daily oral doses of 4 mg RG7314 or placebo for 12 weeks. After an independent safety review, Stage III will be started wherein additional participants will be randomized in 2:1 to receive daily oral doses of 10 mg RG7314 or placebo for 12 weeks. During Stage III, safety will be reviewed by independent safety review twice and if no safety signal is observed, then additional participants will be randomized in 1:1:1 either to receive 1.5 milligrams per day (mg/day) or 10 mg/day RG7314 orally or placebo for 12 weeks in Stage IV.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT01793441 2012-005597-55 BP28420
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	>=18 Years & <= 45 Years	No