ForPatients
by Roche

Autism Spectrum Disorder

A Study to Investigate the Efficacy and Safety of RO5285119 in Participants With Autism Spectrum Disorder (ASD)

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Countries	NCT02901431 BP30153

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

Trial Summary:

For participants enrolled prior to Version 6 of the protocol: This was a Phase II multi-center, randomized, double-blind, 24-week, 3-arm, parallel group, placebo-controlled study to investigate the efficacy, safety, and pharmacokinetics of balovaptan in children and adolescents aged 5-17 years with ASD who are high functioning (intelligence quotient [IQ] greater than or equal to [>=] 70). For participants enrolled according to Version 6 of the protocol: This was a Phase II multi-center, randomized, double-blind, 24-week, parallel group, placebo-controlled, 2-arm study with participants assigned either to a 10 milligram (mg) or equivalent dose of balovaptan, or placebo. All other study parameters remained as stated above. There are three parts to this study: PK Part (Study part 1) included up to 8 weeks of treatment, Main Treatment Part (Study part 2) included 24 week of treatment, and the Open Label Extension Part (Study part 3) included Week 24 to Week 76 of treatment. All participants that completed the 24-week treatment period were eligible to participate in an optional 52-week open-label extension (OLE) during which they received balovaptan treatment.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT02901431 BP30153
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 5 Years & <= 17 Years	No