ForPatients
by Roche

Autism Spectrum Disorder

A Clinical Trial of Balovaptan in Adults with Autism Spectrum Disorder (V1ADUCT)

A Study of Balovaptan in Adults With Autism Spectrum Disorder With a 2-Year Open-Label Extension (V1ADUCT)

Trial Status	Trial Runs In	Trial Identifier
Terminated	6 Countries	NCT03504917 WN39434

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Efficacy, and Safety Study of Balovaptan in Adults With Autism Spectrum Disorder With a 2-Year Open-Label Extension

Trial Summary:

This study will evaluate the efficacy, safety, and pharmacokinetics of 10 mg of oral administration balovaptan once a day (QD) compared with matching placebo in adults (18 years and older) with autism spectrum disorder (ASD).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT03504917 WN39434
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

How does the V1ADUCT clinical trial work? This clinical trial is recruiting people who have an autism spectrum disorder. The aim of this clinical trial is to test whether an experimental medicine called balovaptan can improve social interaction and communication in adults with autism.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must be at least 18 years old and must have a person willing to be your ‘study partner’. Your study partner needs to be a person who knows you well and spends quite a bit of time with you, such as a spouse, partner or other family member, and can attend study visits with you to answer some of the questions asked by the clinical trial doctor. This person can not take part as a participant in the study.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor.

If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of this page. You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care and may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not all need to be done again. You must provide your consent before any tests or procedures are done.

This clinical trial is divided into four parts, or ‘periods’. These parts are called the

- ‘Screening period’ where the clinical trial doctor will check your suitability for the trial, which lasts for approximately 4 weeks
- ‘Treatment period’ where you will be given the trial medicine, which lasts for 6 months (24 weeks)
- ‘Extension period’ where you can continue to participate in this trial after the end of the 24-week treatment period for a further 2 years (104 weeks or 24 months)
- ‘Safety follow-up period’ where the clinical doctor will check if you are having any side effects, which lasts for 3 months

The maximum length of time you will be in this trial is 2 years and 10 months (144 weeks or 34 months).

What happens during the screening period? Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial and what other treatments are available so that you may decide if you still want to take part. While taking part in the clinical trial, women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given one of two different treatments.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given a sugar pill with no active drug (also known as a placebo).

- You will either be given one tablet of the new trial medicine, balovaptan, to swallow once a day throughout the treatment period
- Or you will be given one placebo tablet to swallow once a day throughout the treatment period

There is a fifty/fifty chance to get Balovaptan, and a fifty/fifty chance to get the placebo.

To allow a fair comparison between balovaptan and placebo, you and your clinical trial doctor will be ‘blinded’ to treatment. This means that neither you nor your clinical trial doctor will know whether you are taking the new trial medicine, balovaptan, or the placebo. If your safety is at risk, your clinical trial doctor can find out which drug you are being given.

How often will I be seen in follow-up appointments, and for how long? You will be given the clinical trial treatment for 6 months. You are free to change your mind and stop this treatment at any time. After being given treatment, you will still be seen regularly by the clinical trial doctor. You will need to visit the clinic for an appointment at week 12 and week 24, and these will include a physical examination and blood tests (and a pregnancy test if you are a woman), and your study partner will be also be asked some questions. In addition to the week 12 and week 24 clinic visits, you will be assessed every 2 weeks, either by a clinic visit or by a telephone call, to check if you have any signs of an infection. There are a total of 23 clinic visits if you complete the treatment, extension and safety follow up periods of the study.

At the end of the 24-week treatment period, patients who do not wish to continue into the extension period of the study will complete the safety follow-up, with a telephone call at 1 week then clinic visits at 2 weeks and 12 weeks after completing the 24-week treatment period.

What happens during the extension period? All patients who complete the 24-week treatment period can choose to continue into the extension period of the study. Patients who are willing to enter this period of the study will all receive treatment with one tablet of balovaptan to swallow once a day. During the extension period, patients will visit the clinic every 4 weeks until week 52 (12 months), then every 12 weeks until week 88 (around 8 months later), with further visits at weeks 104, 116 and 128.

At the end of the extension period, patients will complete the safety follow-up, with a telephone call at 1 week then clinic visits at 2 weeks and 12 weeks after completing the extension period.

What happens if I'm unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part. Your doctor may suggest other treatments for you. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT03504917

Inclusion Criteria:

- Subject meets the DSM-5 criteria for ASD for an autism diagnosis and is confirmed using ADOS-2 criteria
- SRS-2, proxy version, total t-score >=66 at screening
- A full scale IQ score >=70 on the WASI®-II
- Subject has an appropriate study partner, in the opinion of the investigator
- For women of childbearing potential: agreement to remain abstinent or use a contraceptive method with a failure rate of <1% per year during the treatment period and for at least 28 days after the last dose of study drug
- Treatment with permitted medications (at a stable dose for 12 weeks before screening) and behavioral therapy regimens (regimens stable for 6 weeks before screening), with the intent that such treatments remain stable throughout the study and with no expected changes before the Week 24 visit

Exclusion Criteria:

- Pregnancy or breastfeeding, or intention to become pregnant during the study
- Previous initiation of new or major change in psychosocial intervention within 6 weeks prior to screening
- Unstable or uncontrolled clinically significant affective or psychotic disorders and/or neurologic disorder that may interfere with the assessment of safety or efficacy endpoints
- Substance use disorders during the last 12 months
- Significant risk for suicidal behavior, in the opinion of the investigator
- Epilepsy or seizure disorder considered not well controlled within the past 6 months or changes in anticonvulsive therapy within the last 6 months
- Clinical diagnosis of peripheral neuropathy
- Within the last 2 years, unstable or clinically significant cardiovascular disease
- Uncontrolled hypertension
- Unexplained syncopal episode within the last 12 months
- Confirmed elevation above upper limit of normal of CK-MB, high sensitivity cardiac troponin T, cardiac troponin I, and/or N-terminal pro B-type natriuretic peptide
- Positive serology results for hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) antibody, or human immunodeficiency virus (HIV) 1 or 2
- History of coagulopathies, bleeding disorders, blood dyscrasias, hematological malignancies, myelosuppression (including iatrogenic), or current major bleeding event
- Concomitant disease or condition that could interfere with, or treatment of which might interfere with, the conduct of the study, or what would, in the opinion of the investigator, pose an unacceptable risk to the subject in this study
- Confirmed clinically significant abnormality in parameters of hematology
- Confirmed clinically significant abnormality in parameters of clinical chemistry, coagulation, or urinalysis
- Medical history of malignancy, if not considered cured

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