ForPatients
by Roche

Autism Spectrum Disorder

The Effect of Hepatic Impairment on the Pharmacokinetics of Balovaptan

Trial Status	Trial Runs In	Trial Identifier
Withdrawn		NCT03912350 WP41045

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:

The Effect of Hepatic Impairment on the Pharmacokinetics of Balovaptan: A Phase I, Multiple-Center, Open-Label Study Following Multiple Daily Oral Doses of Balovaptan in Subjects With Moderate Hepatic Impairment and Healthy Subjects With Normal Hepatic Function

Trial Summary:

This is a multi-center, non-randomized, open-label, parallel group, multiple-dose study to assess the pharmacokinetic, safety, and tolerability of balovaptan in male and female subjects with moderate hepatic impairment compared to healthy subjects with normal hepatic function matched by age (±10 years), sex, and body mass index (BMI; ±20%).

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT03912350 WP41045
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	Accepts Healthy Volunteers

Inclusion Criteria:

Inclusion Criteria for All Participants:

- BMI between 18 and 40 kg/m2, inclusive.
- Women of childbearing potential must either: agree to use one highly effective contraceptive method combined with a barrier method from Screening until 90 days after the last dose of study drug or

practice true abstinence because of the subject's lifestyle choice; be in an exclusively same-sex relationship.
- For men: agreement to use contraceptive measures
- Females of child-bearing potential must refrain from donating ova from Day -1 until 90 days after the safety Follow-up visit. Males must refrain from donating sperm from Day -1 until 90 days after the safety Follow-up visit.

Inclusion Criteria for Participants with Hepatic Impairment:

- Stable, documented moderate liver disease diagnosed >6 months and stable for at least 3 months prior to Screening.
- Participants with moderate hepatic impairment may have medical findings consistent with their hepatic dysfunction. Participants with abnormal findings considered in line with underlying hepatic disease by the Investigator will be eligible.

Inclusion Criteria for Healthy Participants:

- Healthy status is defined by no clinically significant findings from medical and surgical history, a complete physical examination including vital signs, 12-lead ECG, hematology, chemistry, and urinalysis at Screening and/or Day -1 as assessed by the Investigator (or designee). Gilbert's syndrome is acceptable.

Exclusion Criteria:

Exclusion Criteria for All Participants:

- History of significant hypersensitivity, intolerance, or allergy to any drug compound, constituents or excipients of the study drug, food, or other substance, unless approved by the Investigator (or designee).
- History of stomach or intestinal surgery or resection that would potentially alter absorption and/or excretion of orally administered drugs.
- Evidence of hepatorenal syndrome and estimated creatinine clearance range <60 mL/min or abnormal and clinically significant sodium and potassium levels, as determined by the Investigator (or designee).
- Female subjects of childbearing potential with a positive serum pregnancy test at Screening and/or at admission (Day -1), or who are lactating.
- History of drug/chemical abuse within 2 years prior to Screening; current active substance abuse will not be permitted.
- Known personal or family history of congenital long QT syndrome or sudden unexplained death.

Exclusion Criteria for Participants with Hepatic Impairment:

- History within 3 months prior to Screening, or current symptoms of, hepatic encephalopathy Grade 2 and above.
- Evidence of severe ascites.
- Recent history of, or the treatment of, esophageal bleeding within 3 months of first dose, unless banded.
- Participants who have had a porto-systemic shunt.
- Participants who have a history of paracentesis within 3 months prior to Day -1.
- Participants who have a history of unstable diabetes mellitus as evidenced by hemoglobin A1c # 9% at Screening.
- History of alcoholism within 3 months prior to Screening.

- Use of any prescription drugs within 30 days (or within 5 times the elimination half-life, if known, of the medication, whichever is longer) of first dose, with the exception of therapies for hepatic-associated disorders that have been stable for at least 60 days prior to first dose.
- Biliary liver cirrhosis or other causes of hepatic impairment not related to parenchymal disorder and/or disease of the liver.
- Positive result on human immunodeficiency virus (HIV) 1, HIV2, Hepatitis B Surface Antigen (HBsAg).

Exclusion Criteria for Healthy Participants:

- History of presence of liver disease, injury, or dysfunction as indicated by any clinically significant deviations from normal reference ranges in liver function tests, unless approved by the Investigator of designee.
- Participants likely to need prescription medication during the study. Participants who have received any prescribed systemic or topical medication within 30 days (or within 5 times the elimination half-life, if known, of the medication, whichever is longer) of the first dose administration, unless in the opinion of the Investigator the medication will not interfere with the study procedures or compromise safety.
- Any slow-release medicinal formulations considered to still be active within 4 weeks (or within 5 times the elimination half-life of the medication, whichever is longer) prior to the first study drug administration are prohibited, unless in the opinion of the Investigator or designee the medication will not interfere with the study procedures or compromise safety.
- History of alcoholism within 2 years prior to Screening.
- Positive result on HIV 1, HIV2, HBsAg, Hepatitis B core antibody (HBcAb), and/or HCV antibody.
- Signs and symptoms potentially indicative of peripheral neuropathy.