ForPatients
by Roche

Post Traumatic Stress Disorder

Study To Evaluate The Efficacy And Safety Of Balovaptan In Adults With Post-Traumatic Stress Disorder (PTSD)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT05401565 BN43546

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 II, Randomized, Double-Blind, Placebo-Controlled, Two-Arm, Parallel-Group, Multicenter Study To Evaluate The Efficacy And Safety Of Balovaptan In Adults With Post-Traumatic Stress Disorder

Trial Summary:

This study will evaluate the efficacy and safety of 10 mg of oral administration balovaptan once a day (QD) compared with matching placebo in adults with PTSD.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT05401565 BN43546
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 60 Years	No

Inclusion Criteria:

- Participants who have a current diagnosis of PTSD as per DSM-5 criteria, with a score of >/=33 on the PCL-5 at screening
- The index trauma event must have occurred in adulthood, i.e., when the participant was >/=18 years old
- The index trauma event must have occurred at least 6 months prior to screening and no more than 10 years prior to screening
- At baseline, either taking a stable dose of a single antidepressant (SSRI or SNRI) for management of PTSD and have been on that medication for >/=6 weeks at that stable dosage and demonstrating

residual symptoms of PTSD or prior demonstrated lack of tolerability or lack of efficacy and not taking an antidepressant medication at baseline for >/=6 weeks
- Treatment with permitted medications and/or non-pharmacological interventions at a stable dose for 6 weeks prior to screening
- For women of childbearing potential: agreement to remain abstinent or use contraception

Exclusion Criteria:

- Participants who are experiencing ongoing exposure to traumatic events within 3 months of screening
- Participants who are pregnant or breastfeeding, or intending to become pregnant during the study or within 14 days after the final dose of study drug
- Clinically significant psychiatric and/or neurological conditions, which may interfere with the assessment of safety or efficacy endpoints
- Substance use disorders during last 12 months
- Significant risk for suicidal behaviour
- 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 disorders
- Positive serology results for hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) antibody, or human immunodeficiency virus (HIV) 1 or 2
- Moderate or severe hepatic or renal impairment
- History of coagulopathies, bleeding disorders, blood dyscrasias, hematological malignancies, myelosuppression (including iatrogenic)
- Medical history of malignancy, if not considered cured
- Participants who have received treatment with investigational therapy within 8 weeks prior to randomization
- Known hypersensitivity to balovaptan, its components, or any of the excipients used in the formulation