NOVARTIS

A Clinical Trial to Learn About the Effects of VHB937 in People With Amyotrophic Lateral Sclerosis (ALS)

Last Update: Feb 07, 2025
A Phase 2, Randomized, Double-blind, Placebo-controlled Parallel Group Study of VHB937 in Amyotrophic Lateral Sclerosis (ALS) Over 40 Weeks Followed by an Open Label Extension (ASTRALS)
ClinicalTrials.gov Identifier:
NCT06643481
Novartis Reference Number:CVHB937B12201
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This is a multicenter, randomized, double-blind, placebo-controlled, parallel group Phase II study to evaluate the efficacy and safety of VHB937 in participants with early-stage ALS (within 2 years of ALS symptoms onset). The study comprises a core double-blind (DB) 40-week treatment period followed by an open label extension (OLE). The main questions this trial aims to answer in comparing VHB937 to placebo are:

* How long will participants live without needing permanent help from a machine to breathe after starting the trial treatment?
* What is the change in the participant's ability to perform daily activities? This will be measured using a questionnaire called the amyotrophic lateral sclerosis functional rating scale-revised (ALSFRS-R).
* What adverse events are reported during this trial? An adverse event is any sign or symptom that participants have during a trial. Adverse events may or may not be caused by treatments in the trial. The trial doctors will check participants' ALS and general health throughout the trial.

Condition
Amyotrophic Lateral Sclerosis (ALS)
Phase
Phase2
Overall Status
Recruiting
Number of Participants
225
Start Date
Oct 17, 2024
Completion Date
Jun 20, 2028
Gender

All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Other

Placebo

Solution for infusion
Biological

VHB937

VHB937 solution for infusion

Eligibility Criteria

Inclusion Criteria:

* are 18 years of age or older
* male or female, if of childbearing potential, strict contraception required
* have ALS confirmed by the trial doctors using different tests.
* have mild symptoms of ALS as measured by the ALSFRS-R questionnaire (total score \>=30).
* have had symptoms of ALS (weakness) within 24 months of taking part in this trial.
* have not received treatment for ALS or are currently on a stable dose of an approved treatment for ALS.
* have the ability to slowly exhale a volume of air at least 60% of what is expected for the participant's sex, height and age.

Exclusion Criteria:

* Use of other investigational drugs within 5 half-lives of screening, or within 30 days (e.g., small molecules) / or until the expected pharmacodynamic effect has returned to baseline (e.g., biologics), whichever is longer; or longer if required by local regulations.
* Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception while taking study treatment and for 24 weeks after stopping study medication.
* History or current diagnosis of cardiac conditions or ECG abnormalities indicating significant risk of safety for participants in the study.
* Clinical evidence of liver or renal disease/injury.
* Laboratory evidence of hematological abnormalities
* Presence of unstable psychiatric disease, cognitive impairment, neurological disease other than ALS, dementia or substance abuse that would impair ability of the participant to provide informed consent, in the investigator's opinion.
* Participants that reported 'yes' on any suicidal ideation section except for the "Non-Suicidal Self-Injurious Behavior" in the past 2 years as per C-SSRS.
* Presence of cancer, HIV, Hep B, Hep C, tuberculosis, uncontrolled diabetes
* History of active severe respiratory disease, including Chronic Obstructive Pulmonary Disease, interstitial

lung disease or pulmonary fibrosis.
* Taking any prohibited medications

United States

Nerve and Muscle Center of Texas

Recruiting

Houston,Texas,77030,United States

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Aziz Shaibani

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06643481*

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