A Study to Learn About the Treatment LTP001 in Healthy Participants (Part A) and in Participants With PAH (Part B)

Last Update: Jan 03, 2025

A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Single and Multiple Ascending Doses of LTP001 in Healthy Adult Participants (Part A) and to Evaluate the Efficacy and Safety of LTP001 for the Treatment of Participants With Pulmonary Arterial Hypertension (Part B)

ClinicalTrials.gov Identifier:
NCT06649110

Novartis Reference Number:CLTP001A12202

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

A study to learn about the treatment LTP001 in healthy participants (Part A) and in participants with PAH (Part B) The CLTP001A12202 study will explore the safety, tolerability, and pharmacokinetics of LTP001 in healthy volunteers (Part A) and will evaluate the safety and efficacy (Part B) followed by safety extension in participants with pulmonary arterial hypertension.

Condition
Healthy Volunteers, Pulmonary Arterial Hypertension
Phase
Phase1, Phase2
Overall Status
Recruiting
Number of Participants
232
Start Date
Oct 24, 2024
Completion Date
Sep 03, 2026
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

LTP

LTP001
Drug

Placebo

Placebo

Eligibility Criteria

Part A Inclusion Criteria:

* Healthy males and non-child-bearing potential females

Part A Exclusion Criteria:

* Clinically significant ECG or cardiac abnormalities, any surgical or medical condition which might significantly alter the absorption, distribution, metabolism, or excretion of drugs, or which may jeopardize the participant in the study Other protocol-defined inclusion/exclusion criteria may apply.

Part B Inclusion Criteria:

-Confirmed diagnosis of PAH, pre-randomization PVR ≥400 dyn.sec.cm-5, treatment with stable doses of standard-of-care PAH therapies, 6-minute walk distance ≥ 150 m and ≤450 m.

Part B Exclusion Criteria:

Any surgical or medical condition which may place the participant at higher risk from his/her participation in the study Women of child-bearing potential unless they are using highly effective methods of contraception Sexually active males unwilling to use a condom during intercourse while taking study treatment and for 24 hours after stopping study treatment.

History of hypersensitivity to any of the study treatments or excipients

Other protocol-defined inclusion / exclusion criteria may apply

United States

PPD Development LP

Recruiting

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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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