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TRIAL IN PROGRESS: PROSERA, A PHASE 3 STUDY OF THE EFFICACY AND SAFETY OF SERALUTINIB IN ADULTS WITH PULMONARY ARTERIAL HYPERTENSION (PAH)

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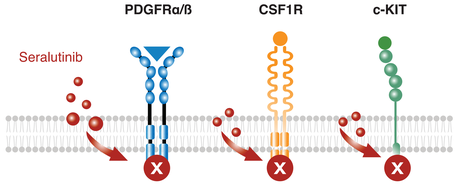
What Is Seralutinib?

- Seralutinib is an investigational medicine specifically designed as a treatment for PAH
- Seralutinib works by blocking proteins that cause inflammation, cell growth ("proliferation"), and scarring ("fibrosis") in the lungs[1,2] (**Figure 1**)
- Seralutinib is a fine dry powder, inhaled using a pocket-sized inhaler device that delivers seralutinib deep into the lungs, where PAH occurs (**Figure 2**)

Figure 1. Seralutinib Blocks Proteins That Contribute to PAH.



Scan the QR code to learn more about seralutinib and how it works.

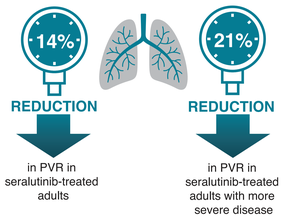
PDGFRα/β, CSF1R, and c-KIT are proteins that are responsible for the overactive inflammation, increased cell growth, and scarring of pulmonary arterioles in PAH.

Figure 2. Dry-powder Inhaler Device Used for Administration of Seralutinib.

The Phase 2 TORREY Study and Open-label Extension (OLE)

- In TORREY (one group received seralutinib, one group received placebo),[3]
  - Seralutinib reduced the pressure in pulmonary blood vessels (also called pulmonary vascular resistance, or PVR) compared to placebo (**Figure 3**)
  - Seralutinib was well tolerated; the most common side effect was cough
- In the OLE (all participants received seralutinib),[4]
  - PVR and exercise capacity continued to improve in some participants treated up to 72 weeks
  - Participants tolerated seralutinib generally well, and the occurrence of cough decreased

Figure 3. Effects of Seralutinib on PVR.

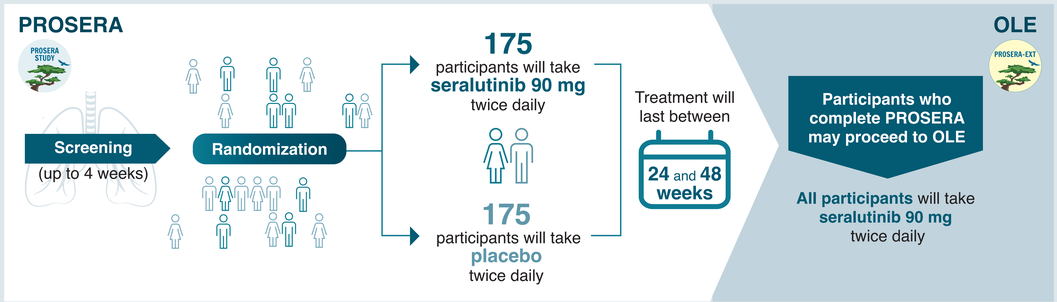


Clinicaltrials.gov study identifier: TORREY, NCT04456998; Open-label Extension, NCT04816604.

The Phase 3 PROSERA Study

- PROSERA was designed to help researchers understand how well seralutinib works as a treatment for PAH and how safe it is for participants with PAH (clinicaltrials.gov identifier: NCT05934526) (**Figure 4**)
- 350 participants will enroll at ~175 study sites in North America, Europe, Latin America, and Asa Pacific
- Participants will receive seralutinib 90 mg or placebo twice daily using a dry-powder inhaler, in addition to already prescribed PAH medication(s)
- Participants who complete PROSERA may consider enrollment into a separate open-label extension (OLE) study, in which all participants will receive seralutinib
- The OLE will continue to evaluate how well inhaled seralutinib works and how well it is tolerated

Figure 4. PROSERA Study Design.



Who can participate in PROSERA?

- Adults 18 to 75 years old
- Group 1 pulmonary hypertension (PAH)
- WHO Functional Class (FC) II or III
- Pulmonary vascular resistance (PVR) ≥400 dyne•s/cm^5
- 6-minute walk distance (6MWD) 150 to 475 meters
- Stable treatment with at least one standard-of-care PAH medicine

NT-proBNP, N-terminal pro-brain natriuretic peptide; REVEAL, Registry to Evaluate Early and Long-term PAH Disease Management; WHO, World Health Organization.

What will be studied in PROSERA?

How well does seralutinib work?

- Change in exercise capacity (6MWD) from the beginning of PROSERA to Week 24
- Decrease in WHO FC or maintenance of WHO FC II
- Increase in 6MWD ≥10% or ≥30 meters
- Change in NT-proBNP, a protein that measures stress on the heart, at Week 24 compared to the beginning of PROSERA
- Proportion of participants with ≥1 point decrease in REVEAL Lite 2 risk score versus Baseline at Week 24

How well is seralutinib tolerated?

- What side effects are seen during PROSERA and how often?

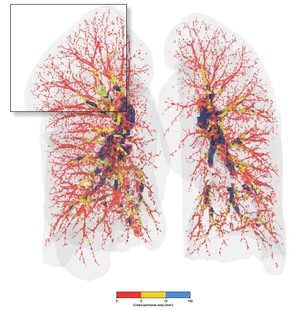
WHAT DOES IT MEAN?

Functional Class: 4 FCs describe how severe a patient's symptoms are. They range from "FC I = symptom-free when physically active or resting," to "FC IV = symptoms at rest and severe symptoms with an activity."

REVEAL Lite 2 risk score: A scoring system that is used to understand the severity of PAH and to help manage it effectively. It uses 6 easy-to-measure factors, including FC, vital signs, 6MWD, and others to assign a score.

PROSERA FRI Substudy

- Functional respiratory imaging (FRI) is a technology that uses computed tomography, or CT, scans to visualize small blood vessels in the lungs, how they change over time, and how much blood they carry
- In the phase 2 TORREY study, researchers found that seralutinib improved the volume of these blood vessels, which indicates that blood may potentially flow better through the lungs
- In PROSERA, researchers will continue to investigate the effects of seralutinib on improving the small blood vessels, which are narrowed by PAH



Representative image.

SUMMARY

- Seralutinib is an investigational, inhaled, medicine that blocks proteins that contribute to inflammation, proliferation, and fibrosis related to PAH progression
- Seralutinib was designed specifically for the treatment of PAH and formulated for administration by dry-powder inhaler to achieve delivery deep into the lungs where PAH occurs
- The phase 3 PROSERA study is enrolling participants to further evaluate the efficacy and safety of seralutinib in adults with PAH

Participation in clinical trials is needed to advance the science in PAH. To learn more about the PROSERA study, go to www.proserastudy.com or scan the QR code

References: **1** Pullamsetti SS, et al. *Int J Mol Sci*. 2023;24(16):12653. **2** Galkin A, et al. *Eur Respir J*. 2022;60(6):2102356. **3** Frantz RP, et al. *Lancet Respir Med*. 2024;12(7):523-534. **4** Sitbon O, et al. *Am J Respir Crit Care Med*. 2024;209:A1011.

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