**BACKGROUND**

- Abnormal signaling of PDGFRα/β, CSF1R, and c-KIT, and BMPR2 deficiency, drive cellular overgrowth in the lung vasculature and play key roles in PAH progression \(^1\)  \(^2\)  \(^3\)  \(^4\)  \(^5\). Seralutinib was evaluated in two preclinical animal models, monocrotaline/pneumonectomy \(^4\) and sugen 5416/hypoxia \(^5\), that targets these pathways and modulates lung tissue vs plasma \(^5\).

- Seralutinib was evaluated in two preclinical animal models, monocrotaline/pneumonectomy \(^4\) and sugen 5416/hypoxia \(^5\), that targets these pathways and modulates lung tissue vs plasma \(^5\).

- Seralutinib is a unique, inhaled, small-molecule kinase inhibitor that targets these pathways and modulates lung tissue vs plasma \(^5\).

**OBJECTIVES**

- **PRIMARY**
  - Determine effect of seralutinib on exertional capacity
  - Change in exercise capacity from Baseline to Week 24 (Δ6MWD)

- **SECONDARY**
  - Change in six-minute walk distance from Baseline to Week 24 (Δ6MWD)
  - Evidence of chronic thromboembolic disease or acute pulmonary embolism
  - WHO Pulmonary Hypertension Group 2–5
  - HIV-associated PAH
  - History of left-sided heart disease and/or clinically significant cardiac disease
  - Inhaled prostanooids
  - Use of anticoagulants

**ENDPOINTS**

- Change in pulmonary vascular resistance from Baseline to Week 24

**SELECTED INCLUSION CRITERIA**

- Diagnosis of symptomatic PAH
- 6MWD > 150 meters and ≤ 550 meters
- WHO FC I or II
- Treatment with standard of care PAH background therapies, including PGIs
- Pulmonary vascular resistance from Baseline to Week 24 (Δ6MWD)
- Evidence of chronic thromboembolic disease or acute pulmonary embolism
- WHO Pulmonary Hypertension Group 2–5
- HIV-associated PAH
- History of left-sided heart disease and/or clinically significant cardiac disease
- Inhaled prostanooids
- Use of anticoagulants

**SELECTED EXCLUSION CRITERIA**

- Use of anticoagulants
- HIV-associated PAH
- Evidence of chronic thromboembolic disease or acute pulmonary embolism
- WHO Pulmonary Hypertension Group 2–5
- HIV-associated PAH
- History of left-sided heart disease and/or clinically significant cardiac disease
- Inhaled prostanooids
- Use of anticoagulants

**REFERENCES**


**SUMMARY**

- Seralutinib is a unique, inhaled, small-molecule kinase inhibitor that targets PDGFRα/β, CSF1R, and c-KIT, and modulates BMPR2.

- The inhaled route of administration for seralutinib targets the diseased pulmonary arteries at doses predicted to be locally effective while limiting systemic exposure which may reduce the risk of adverse events.

- A phase 2 trial (TORREY; NCT04456998) in subjects with WHO Group 1 PAH is ongoing.

- Eligible subjects may participate in a 72-week open-label extension study.

**TORREY STUDY**

- The TORREY study is a randomized, double-blind, placebo-controlled trial (NCT04456998) designed to examine the efficacy and safety of inhaled seralutinib in subjects with PAH over a 24-week course of treatment.

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**PRESENTED AT**

10th Annual PAH Global Digital Symposium Presented at the PHA 2022 International PH Conference and Scientific Sessions, June 10-12, Atlanta, GA