Re-Spire: A Phase 3, Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Safety and Efficacy of L606 (Treprostinil Liposome Inhalation Suspension) in Pulmonary Hypertension With Interstitial Lung Disease (PH-ILD) Participants

Poster #PS-37

Liquidia®

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Introduction

- Pulmonary hypertension (PH) is a common and serious complication of interstitial lung disease (ILD) that is associated with reduced exercise capacity, impaired quality of life, and increased mortality and remains an area of substantial unmet therapeutic need despite recent advances[1]
- L606 is an investigational extended-release formulation of treprostinil designed for twice-daily administration, with the potential to provide continuous 24-hour therapeutic coverage[2]

Re-Spire Objective

- To evaluate whether L606 improves exercise capacity compared with placebo in PH-ILD while maintaining acceptable safety and tolerability

Study Rationale/Why L606

Extended-release
treprostinil liposome inhalation suspension

Pulmonary delivery
targets the site of disease

Twice-daily dosing
for convenience and consistency

Potential for continuous
24-hour therapeutic coverage

Re-Spire Methods

Re-Spire
(NCT07285655)

Global phase 3 trial

~344 adults with PH-ILD

Randomized 1:1

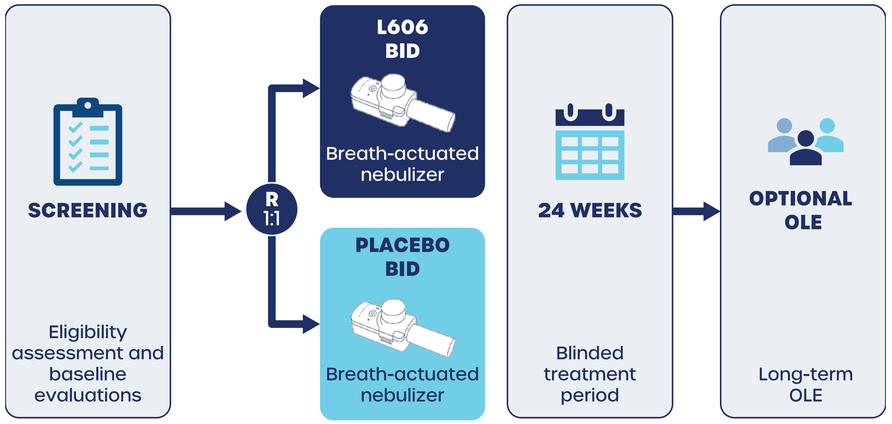
L606 vs placebo

Twice daily administration

Breath-actuated nebulizer

24-week blinded treatment period

Optional long-term OLE



RANDOMIZATION STRATIFIED BY:
- CPFE absence/presence
- Background phosphodiesterase-5 inhibitor use
- Baseline 6MWD

6MWD, 6-minute walk distance; BID, twice daily; CPFE, combined pulmonary fibrosis and emphysema; OLE, open-label extension; PH-ILD, pulmonary hypertension with interstitial lung disease; R, randomization.

Key Takeaway

- Re-Spire is designed to determine whether twice-daily pulmonary delivery of treprostinil liposome inhalation suspension can lead to clinically meaningful improvements in functional capacity while maintaining an acceptable safety and tolerability profile

Re-Spire Endpoints

PRIMARY ENDPOINT
Change from baseline to Week 16 in 6MWD measured at peak exposure

KEY SECONDARY ENDPOINTS
- Time to clinical worsening
- Change in peak 6MWD at Week 24
- Change in trough 6MWD at Week 16

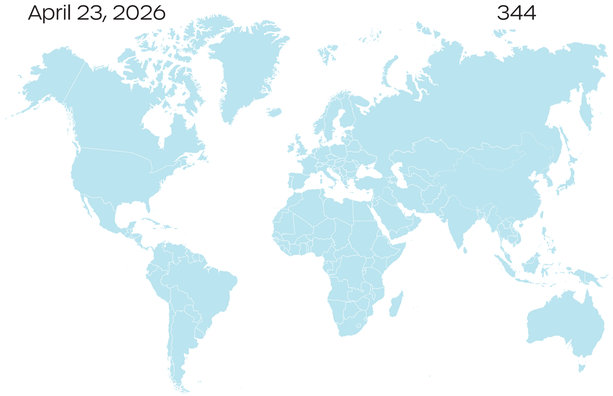
OPTIONAL SUBSTUDY
Haemodynamic outcomes

ADDITIONAL ENDPOINTS
- Cardiopulmonary outcomes
- Biomarkers
- Patient-reported outcomes
- Safety assessments

6MWD, 6-minute walk distance.

Re-Spire Study Sites

- **Study start date:** April 23, 2026
- **Estimated enrollment:** 344



For the most up-to-date list of study locations and to learn more, scan the QR code to visit ClinicalTrials.gov.

CONCLUSION

- This pivotal study, which commenced in April 2026 and is actively recruiting, has the potential to establish a meaningful new treatment option for this vulnerable patient population, addressing a significant unmet medical need in PH-ILD

References

1. Waxman AB, et al. *Eur Respir Rev.* 2022;31(165):210220.
2. Habib N, et al. An Open-Label Safety Study of L606 (Liposomal Treprostinil) in Patients With PAH and PH-ILD. Presented at: American Thoracic Society International Conference; May 24, 2024; San Diego, USA.

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Author Disclosures

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