



Gossamer Bio Announces Topline Results from the Phase 3 PROSERA Study Evaluating Seralutinib in Pulmonary Arterial Hypertension

February 23, 2026

- Seralutinib demonstrated a placebo-adjusted improvement in Six-Minute Walk Distance (6MWD) of +13.3 meters at Week 24 ($p = 0.0320$), missing the prespecified alpha threshold of 0.025 -
- At week 24, patients receiving seralutinib had a median change of +28.2 meters from baseline, while patients receiving placebo had a median change from baseline of +13.5 meters -
- Consistent with the TORREY Study, prespecified intermediate and high-risk subgroup ($n = 234$) showed a +20.0 meter placebo-adjusted 6MWD improvement ($p = 0.0207$), with 3 of 4 key secondary endpoints achieving $p < 0.0125$ -
- Overall treatment effect was most pronounced in North America ($n = 75$), with a +25.9m placebo-adjusted improvement in 6MWD ($p = 0.0573$) -
 - Generally well tolerated - safety consistent with prior experience -
 - Gossamer plans to meet with the U.S. FDA to discuss the path forward -
 - Gossamer to host a conference call today, Monday, February 23rd at 8:30am EST -

SAN DIEGO--(BUSINESS WIRE)--Feb. 23, 2026-- [Gossamer Bio, Inc.](#) (Nasdaq: GOSS) a biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD), today announced topline results for the PROSERA Phase 3 Study of seralutinib in patients with PAH. Gossamer Bio and the Chiesi Group are jointly developing seralutinib under a global collaboration agreement.

At Week 24, patients receiving seralutinib had a median change of +28.2 meters in 6MWD from baseline, while patients receiving placebo had a median change from baseline in 6MWD of +13.5 meters. The estimated Hodges-Lehmann treatment effect was +13.3 meters, with a p-value of 0.0320, which did not meet the prespecified threshold on the primary endpoint ($\alpha = 0.025$); therefore, p-values for the key secondary endpoints cannot be evaluated for statistical significance. All p-values herein are nominal. All four key secondary endpoints favored seralutinib versus placebo in the overall population.

Consistent with the Phase 2 TORREY Study, seralutinib delivered a compelling signal in the prespecified intermediate- and high-risk subgroup ($n = 234$), as defined by the REVEAL 2 Lite Risk Score ≥ 6 at screening, with a +20.0m placebo-adjusted improvement in 6MWD ($p = 0.0207$). Three of four key secondary endpoints also demonstrated a p-value below 0.0125, underscoring seralutinib's activity in patients with higher risk.

"While we are disappointed to have narrowly missed the stringent prespecified statistical threshold for our primary endpoint, the result still clears the traditional 0.05 p-value, and we believe these data clearly demonstrate seralutinib is an active drug in patients with PAH," said Faheem Hasnain, Chairman, Co-Founder, and CEO of Gossamer Bio.

"We are also pleased by the clinically meaningful improvements observed in intermediate- and high-risk patients who are at an increased risk of significant morbidity and mortality events and represent a population with a high unmet need. From a clinical development perspective, this is not a narrow or exploratory finding. Seralutinib has once again demonstrated a statistically robust and clinically meaningful signal in higher-risk patients, consistent with the TORREY Study, which is a clearly defined and readily identifiable population. This finding is compelling on its own."

"Altogether, these data support the conclusion that seralutinib demonstrated greater activity in patients with more advanced disease. This is even more impressive given how heavily treated the PROSERA population was, including 55% of patients on triple or quadruple background PAH therapy and 61% on background prostacyclin therapy."

"We are deeply grateful to the patients, investigators, and clinical teams whose participation made this study possible. Given the significant unmet need in PAH, and seralutinib's differentiated, nonvasodilatory mechanism, we believe these results warrant further discussions with the FDA regarding a potential path forward."

Additional Topline Efficacy Results

A key secondary endpoint, change in NT-proBNP at Week 24, demonstrated an estimated location shift of -120.4 ng/L compared with placebo (p=0.0002) in the overall population, with separation between the arms favoring seralutinib observed starting at Week 4 (-96.0 ng/L; p=0.0002). Key secondary endpoints time-to-clinical worsening (TTCW), clinical improvement and proportion of patients with a one point or greater reduction in REVEAL Lite 2 Risk Score all favored seralutinib as compared to placebo in the overall population.

In a prespecified subgroup analysis of patients with REVEAL Lite 2 score ≥ 6 at screening, corresponding to intermediate- and high-risk patients, seralutinib demonstrated a pronounced and clinically meaningful response profile across the primary and key secondary endpoints. All key secondary endpoints favored seralutinib, with placebo-adjusted effects including NT-proBNP at Week 24 (location shift = -265.8 ng/L; p=0.0002), ≥ 1 -point improvement in REVEAL Lite 2 risk score at Week 24 (odds ratio = 2.033; p=0.0083), clinical improvement at Week 24 (odds ratio = 3.318; p=0.0101), and TTCW through Week 48 (hazard ratio = 0.744; p=0.4360).

Notably, in patients with connective tissue disease-associated PAH (CTD-APAH), seralutinib demonstrated a robust improvement in six-minute walk distance, achieving a placebo-adjusted gain of +37.0 meters at Week 24 (n = 87; p=0.0104), indicating a strong treatment effect in this clinically challenging subgroup.

Safety and Tolerability Results

Overall, seralutinib was generally well tolerated in the PROSERA Study. Treatment-emergent adverse events (TEAEs) were reported in 86.5% of patients receiving seralutinib and 80.5% of patients receiving placebo. Treatment-emergent serious adverse events (SAEs) occurred in 16.0% of patients receiving seralutinib and 18.9% of patients receiving placebo. Transaminase elevations of three times or greater of the upper limit of normal were observed in 13% of patients receiving seralutinib and 1% of patients receiving placebo. The most frequently reported adverse event in patients treated with seralutinib was cough, reported in 37.0% of patients.

Next Steps

Based on these results, Gossamer Bio expects to meet with the U.S. FDA to discuss the path forward for seralutinib in pulmonary arterial hypertension. The Company is pausing enrollment into the SERANATA Study to evaluate the impact of PROSERA results, particularly regional discrepancies in placebo response.

Additionally, PROSERA results from the CT functional respiratory imaging (FRI) substudy are expected in the coming weeks and are anticipated to provide additional insight into seralutinib's treatment effect, including pulmonary blood volume distribution.

Conference Call and Webcast

Gossamer's management team will host a conference call and live audio webcast to discuss the Phase 3 PROSERA Study topline results, today at 8:30 am EST.

The live audio webcast may be accessed through the "Events / Presentations" page in the "Investors" section of the Company's website at www.gossamerbio.com. Alternatively, the conference call may be accessed through the following:

Dial-in Number: 1-800-715-9871

Conference Reference: Gossamer Bio PROSERA Study Results Announcement Call

Live Webcast: <https://edge.media-server.com/mmc/p/9rbwvj0s>

A replay of the audio webcast will be available for 30 days on the "Investors" section of the Company's website, www.gossamerbio.com.

PROSERA Study Overview and Baseline Characteristics

The PROSERA Study is a double-blind, placebo-controlled, global registrational clinical trial evaluating seralutinib in PAH patients, on top of background PAH therapy. Patients received blinded treatment for up to 48 weeks. The Phase 3 study enrolled 390 patients with WHO Functional Class (FC) II or III PAH, with 197 randomized to the seralutinib arm and 193 randomized to the placebo arm. 55% of the enrolled patients were on background triple or quadruple PAH therapy, and 61% were on background prostacyclin therapy. The treatment and placebo arms were generally well balanced.

About Seralutinib

Seralutinib is a novel, investigational, inhaled tyrosine kinase inhibitor designed to target key growth factor receptors implicated in PAH, including the platelet-derived growth factor receptor (PDGFR), colony-stimulating factor 1 receptor (CSF1R), and c-KIT. Delivered via dry powder inhalation, seralutinib aims to provide direct pulmonary delivery for enhanced local activity while minimizing systemic exposure. Through the inhibition of these signaling pathways, seralutinib is intended to address inflammation, proliferation and fibrosis, key drivers of PAH disease progression.

About Pulmonary Arterial Hypertension

PAH is a rare, progressive, and often fatal disease marked by elevated blood pressure in the arteries connecting the right side of

the heart to the lungs. Abnormal growth and remodeling of the small pulmonary blood vessels restrict blood flow, increasing strain on the right heart and potentially leading to heart failure. Common symptoms include shortness of breath, fatigue, chest pain, dizziness, and fainting. As the disease advances, patients may experience blood clots within the lungs and declining exercise capacity, ultimately resulting in severe breathlessness and risk of death.

About Gossamer Bio

Gossamer Bio is a biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease.

Forward-Looking Statements

Gossamer cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the therapeutic potential and market opportunity of seralutinib in PAH or PH-ILD, plans to put the ongoing Phase 3 SERANATA Study on hold, the expected plan to discuss topline results with the FDA and the potential to identify a development path forward for seralutinib. The inclusion of forward-looking statements should not be regarded as a representation by Gossamer that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Gossamer's business, including, without limitation: topline results Gossamer reports is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; Gossamer may not be able to identify a development path forward for seralutinib, whether as a result of FDA feedback or otherwise, and any path forward may require additional capital and other resources or may limit the commercial opportunity for seralutinib; Gossamer may need to evaluate its current workforce in light of potential development paths for seralutinib; potential delays in the commencement, enrollment and completion of clinical trials; comparative safety information is not based on a head-to-head comparison and differences exist between study designs and subject characteristics which could confound the results; the Company's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the results of preclinical studies and early clinical trials with seralutinib are not necessarily predictive of future results; the success of any future Gossamer's clinical trials and preclinical studies for seralutinib; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of seralutinib that may limit its development, regulatory approval and/or commercialization, or may result in clinical holds, recalls or product liability claims; Gossamer's ability to obtain and maintain intellectual property protection for seralutinib; Gossamer's ability to comply with its obligations in collaboration agreements with third parties or the agreements under which it licenses intellectual property rights from third parties; Gossamer may use its capital resources sooner than it expects; and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Gossamer undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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