Gossamer Bio Announces Completion of Enrollment in Registrational Phase 3 PROSERA Study for the Treatment of PAH

June 16, 2025

- Enrollment Completed in Ongoing Registrational PROSERA Phase 3 Study in PAH -

- Topline Results Announcement from PROSERA Phase 3 Expected in February 2026 -

- Blinded Preliminary Baseline Characteristics Align with Intended Study Population -

SAN DIEGO--(BUSINESS WIRE)--Jun. 16, 2025-- Gossamer Bio, Inc. (Nasdaq: GOSS), a late-stage, clinical 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 enrollment completion for the ongoing, global registrational Phase 3 PROSERA Study evaluating seralutinib in Functional Class II and III PAH patients. Gossamer Bio and the Chiesi Group are jointly developing seralutinib under a global collaboration agreement.

“Completing enrollment for the Phase 3 PROSERA Study represents an important step forward in our mission to develop seralutinib as a potential first-in-class treatment option for PAH,” said Faheem Hasnain, CEO, Chairman and Co-founder of Gossamer Bio. “We are deeply grateful to the patients, caregivers, and investigators who made this possible through their dedication and partnership.”

Mr. Hasnain continued, “Building on insights from the Phase 2 TORREY Study, we focused on selecting a patient population that aligns closely with the study’s objectives and is more likely to exhibit a clinically significant benefit in 24 weeks. Given the preliminary baseline characteristics of PROSERA, we firmly believe that we have accomplished this patient selection goal. We are eager to be able to share topline results from this registrational study early next year.”

Enrollment in the ongoing Phase 3 PROSERA Study was closed on June 11th. The Phase 3 PROSERA Study is a double-blind, placebo-controlled, global registrational clinical trial evaluating seralutinib in PAH patients, on top of background PAH therapy. Patients are assigned 1:1 to either the seralutinib or placebo arms. Patients receive blinded treatment for up to 48 weeks.

The primary endpoint of the PROSERA Study is change in six-minute walk distance (6MWD) from baseline as compared to placebo at week 24. Included in the key secondary endpoints is time to clinical worsening, as compared to placebo, up to week 48. In addition to other secondary and exploratory endpoints, safety and tolerability will be evaluated.

The patient population enrolled in PROSERA aligns with the target demographic, as evidenced by the preliminary baseline characteristics. The PROSERA Study utilizes enrichment criteria, including the REVEAL Lite 2 Risk Score and other criteria, to identify patients more likely to show a greater magnitude of effect on 6MWD at week 24, as informed by the Phase 2 TORREY study. We expect to announce topline results from the ongoing Phase 3 PROSERA Study in February 2026.

Baseline Characteristics: PROSERA Study (Phase 3) v. TORREY Study (Phase 2)

	PROSERA Phase 3*	TORREY Phase 2
Study Participants	n = 390	n = 86
Mean 6MWD	374 meters	408 meters
Mean NT-proBNP	987 ng/L	628 ng/L
Functional Class III Patients	289 (74%)	36 (42%)
Geographic Distribution	North America: 75 (19%) Rest of World: 315 (81%)	North America: 59 (69%) Rest of World: 27 (31%)
**Baseline characteristics are preliminary and subject to change.*		

About Gossamer Bio

Gossamer Bio is a late-stage, clinical 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. Its goal is to be an industry leader in, and to enhance the lives of patients living with, pulmonary hypertension.

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 anticipated timing of a data readout from our Phase 3 PROSERA Study; the potential or likelihood for a meaningful data readout from our PROSERA Study; and the first-in-class commercial potential of 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: potential delays in the commencement, enrollment and completion of clinical trials; disruption to our operations from unexpected events, including clinical trial delays; 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 are not necessarily predictive of future results; the success of 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; unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may adversely affect our business and financial condition and the broader economy and biotechnology industry; 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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