Trevi Therapeutics Announces Completion of End-of-Phase 2 Meeting with the FDA, Gaining Alignment for Its Development Program for Idiopathic Pulmonary Fibrosis-Related Chronic Cough

March 9, 2026

The Company will conduct two Phase 3 clinical trials of nalbuphine ER for the treatment of patients with IPF-related chronic cough

First pivotal trial is on track to initiate in the second quarter of 2026, with the second pivotal trial expected to initiate in the second half of 2026

NEW HAVEN, Conn., March 09, 2026 (GLOBE NEWSWIRE) -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of chronic cough in patients with idiopathic pulmonary fibrosis (IPF), non-IPF interstitial lung disease (non-IPF ILD), and refractory chronic cough (RCC), today announced the results of its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). At the meeting, the Company gained overall alignment on the plan for the remaining development program. The Company plans to conduct two pivotal Phase 3 clinical trials and obtained agreement on the remaining Phase 1 clinical studies that the Company expects to conduct to support the New Drug Application (NDA) submission. The Company plans to conduct the Phase 3 trials in parallel with each other and is on track to initiate the first Phase 3 trial in the second quarter of 2026 and the second Phase 3 trial in the second half of 2026.

"We very much appreciate the FDA's careful review of our IPF-related chronic cough program to date and the highly collaborative discussions we had during the meeting," said James Cassella, PhD, Chief Development Officer of Trevi Therapeutics. "We clarified the path forward for our Phase 3 program and received useful guidance on the remaining Phase 1 studies to be conducted. We are well positioned to initiate pivotal parallel Phase 3 trials beginning in the second quarter of 2026 and to execute on the remaining development program."

Jennifer Good, President and CEO of Trevi Therapeutics, added, "The End-of-Phase 2 meeting was an important milestone for the Company, and we are grateful for the guidance from the FDA. With no FDA-approved therapies for IPF-related chronic cough, it remains highly burdensome for patients living with IPF and is a condition which has historically had limited options. Our team is focused on advancing Haduvio for these patients and potentially addressing this urgent unmet need."

The Phase 3 trials will both be randomized, double-blind, placebo-controlled, multicenter, global trials evaluating the safety and efficacy of nalbuphine ER tablets, with 54 mg twice-a-day (BID) dosing, for the treatment of patients with IPF-related chronic cough. Patients enrolled in the trials will be randomized 2:1 to either nalbuphine ER or placebo. The first of the two Phase 3 trials is planned to enroll approximately 300 patients with IPF-related chronic cough and have 52 weeks of fixed dosing, with the primary endpoint at 24 weeks of fixed dosing. The other Phase 3 trial is planned to enroll approximately 130 patients with IPF-related chronic cough and have 12 weeks of fixed dosing. The primary efficacy endpoint for both trials will be the relative change from Baseline in 24-hour cough frequency (coughs per hour), as determined by an objective cough monitor, for nalbuphine ER compared with placebo. These trial designs are subject to final review of the protocols by the FDA.

About Idiopathic Pulmonary Fibrosis (IPF)-Related Chronic Cough
Chronic cough in patients with IPF is a condition with high unmet need and no FDA-approved therapies. There are ~150,000 U.S. patients with IPF, and two-thirds of these patients are faced with uncontrolled chronic cough. The impact of chronic cough is significant, with patients coughing up to 1,500 times per day. This consistent cough, and any associated damage, may lead to a higher risk of morbidity and mortality, including worsening disease, a higher risk of progression, increased respiratory hospitalizations, and a decline in patients' quality of life.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine extended-release) for the treatment of chronic cough in patients with idiopathic pulmonary fibrosis (IPF), non-IPF interstitial lung disease (non-IPF ILD), and refractory chronic cough (RCC). Haduvio is the first and only investigational therapy to show a statistically-significant reduction in cough frequency in clinical trials across both patients with IPF chronic cough and in patients with RCC. Haduvio acts on the cough reflex arc both centrally and peripherally as a kappa agonist and a mu antagonist (KAMA), targeting opioid receptors that play a key role in controlling chronic cough. Nalbuphine is not currently scheduled by the U.S. Drug Enforcement Agency.

Trevi intends to propose Haduvio as the trade name for oral nalbuphine ER. Its safety and efficacy have not been evaluated by any regulatory authority.

For more information, visit www.TreviTherapeutics.com and follow Trevi on X (formerly Twitter) and LinkedIn.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties and actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding Trevi's business plans and objectives, including future plans or expectations for Haduvio and plans and timing with respect to clinical trials, statements regarding FDA guidance, and other statements containing the words “believes,” “anticipates,” “plans,” “expects,” and similar expressions. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties regarding the success, cost and timing of Trevi’s product candidate development activities and clinical trials; the risk that positive data from a clinical trial may not necessarily be predictive of the results of later clinical trials in the same or a different indication; uncertainties regarding Trevi's ability to execute on its strategy; uncertainties with respect to regulatory authorities' views as to the data from Trevi's clinical trials and next steps in the development path for Haduvio in the United States and foreign countries; uncertainties inherent in estimating Trevi's cash runway, future expenses and other financial results, including Trevi's ability to fund future operations, including clinical trials; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended September 30, 2025 filed with the Securities and Exchange Commission and in subsequent filings made by the Company with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Trevi undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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