Trevi Therapeutics Provides Strategic Updates Ahead of Annual LifeSci Partners Corporate Access Event Held During the J.P. Morgan Healthcare Conference

January 8, 2026

FDA End-of-Phase 2 meeting scheduled to take place in the first quarter of 2026 for the chronic cough program in patients with idiopathic pulmonary fibrosis

Phase 2b refractory chronic cough trial planned to initiate in the first half of 2026

NEW HAVEN, Conn., Jan. 8, 2026 /PRNewswire/ -- 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 strategic updates ahead of its participation in the 15th Annual LifeSci Partners Corporate Access Event taking place in San Francisco, CA, from January 12-14, 2026. This event will be held during the week of the annual J.P. Morgan Healthcare Conference.

"We are excited as we begin 2026 to continue the clinical development of Haduvio in our key chronic cough indications," said Jennifer Good, President and CEO of Trevi Therapeutics. "We have an End-of-Phase 2 meeting scheduled with the FDA, and we hope to align on our development program for the treatment of chronic cough in patients with IPF and then initiate that program. We have also been preparing to initiate a Phase 2b trial in RCC in the first half of this year. We expect that 2026 will be a year of focused execution at Trevi as we work to advance Haduvio a step closer to patients suffering from these debilitating chronic cough conditions."

Key Company Highlights

- Chronic Cough in IPF
  - The Company was granted an End-of-Phase 2 meeting by the FDA, scheduled to take place in the first quarter of 2026. This meeting will discuss the clinical development and regulatory pathway for the New Drug Application of nalbuphine ER for the treatment of chronic cough in patients with IPF. Following this meeting, the Company expects to initiate its Phase 3 program of nalbuphine ER in this patient population in the first half of 2026.
- Refractory Chronic Cough
  - The Company plans to initiate a Phase 2b trial in patients with RCC in the first half of 2026.
- David Hastings, the new Chief Financial Officer for Trevi Therapeutics, will attend the LifeSci Partners Corporate Access Event along with other members of the senior management team.

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.

Chronic cough in patients with IPF and non-IPF ILD 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. Additionally, there are ~228,000 U.S. patients with non-IPF ILD, with 50-60% having 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.

RCC is a condition with high unmet need and no FDA-approved therapies. RCC is defined as a persistent cough lasting >8 weeks despite treatment for an underlying condition (i.e., asthma, gastroesophageal reflux disease, non-asthmatic eosinophilic bronchitis, upper airway cough syndrome, or post-nasal drip) and includes unexplained chronic cough. There are ~2-3 million U.S. patients with RCC, and it is believed to be associated with cough reflex hypersensitivity involving both the central and peripheral nervous systems. RCC is highly debilitating and may impact patients physically, psychologically, and socially.

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, expectations regarding Trevi's sufficiency of capital, 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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