Trevi Therapeutics Announces Oral Presentation and Multiple Posters Accepted at the American Thoracic Society (ATS) 2026 International Conference

April 30, 2026

Primary and subgroup analysis from the Phase 2b CORAL trial of nalbuphine ER for the treatment of patients with IPF-related chronic cough accepted for oral presentation, including key subgroup analyses by baseline cough count and background anti-fibrotic use

An exploratory post-hoc analysis of the effects of nalbuphine ER and placebo on cough bouts from the Phase 2b CORAL trial in patients with IPF-related chronic cough and the Phase 2a RIVER trial in patients with refractory chronic cough

Drug–drug interaction data from a Phase 1 study evaluating pharmacokinetics and safety following co-administration of nalbuphine ER with pirfenidone or nintedanib

NEW HAVEN, Conn., April 30, 2026 (GLOBE NEWSWIRE) -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing the investigational therapy 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 that it will deliver an oral presentation and present multiple abstracts at the American Thoracic Society (ATS) 2026 International Conference, taking place from May 15 – 20, 2026, in Orlando, Florida.

Oral Presentation

Abstract: A Phase 2b Trial (CORAL) of Nalbuphine Extended-release Tablets in Patients with Idiopathic Pulmonary Fibrosis Experiencing Chronic Cough: Primary and Subgroup Analyses
Oral Presentation Session: B95 Fibrosis, Cough, and Inflammation: Treatment Strategies in ILD
Date & Time: May 18, 2:27 p.m. to 2:39 p.m. ET
Location: W304 E-H (Level III, OCCC West Concourse)
Presenter: Philip L. Molyneaux, MD, PhD

Poster Presentations

Abstract: Pharmacokinetics and Safety Following Co-Administration of Nalbuphine Extended-Release with Pirfenidone or Nintedanib: A Phase 1 Drug-Drug Interaction Study
Poster Session: A75 Late Breaking Abstracts in Clinical Problems
Date & Time: May 17, 11:30 a.m. to 1:15 p.m. ET
Location: Area L, Halls WA2-WA3 (Level I, OCCC West Concourse)
Presenter: James Cassella, PhD

Abstract: The Effect of Nalbuphine Extended Release on Cough Bouts in Patients with Idiopathic Pulmonary Fibrosis from a Phase 2b Randomized Clinical Trial (CORAL)
Poster Session: A110 Closing the Gap: Advances in Pulmonary Fibrosis
Date & Time: May 17, 2:15 p.m. to 4:15 p.m. ET
Location: West F3 (Level II, OCCC West Concourse)
Presenter: Jaclyn Smith, PhD, MBChB

Abstract: Nalbuphine Extended Release Reduces Cough Bouts in Patients with Refractory Chronic Cough in the Phase 2a RIVER Trial
Poster Session: B29 The Latest in Airway Symptoms and Disease
Date & Time: May 18, 9:15 a.m. to 11:15 a.m. ET
Location: W414AB (Level IV, OCCC West Concourse)
Presenter: Jaclyn Smith, PhD, MBChB

Abstract: Evaluating the Burden of Chronic Cough in Patients with Interstitial Lung Disease: A US Survey-based Analysis of Its Effects on Daily Life and Emotional and Social Well-being
Poster Session: B39 Breath and Burden: Diffuse Lung Diseases and Daily Life
Date & Time: May 18, 11:30 a.m. to 1:15 p.m. ET
Location: Area A, Halls WA2-WA3 (Level II, OCCC West Concourse)
Presenter: Jeffrey J. Swigris, DO, MS

Abstract: The Effect of Nalbuphine Extended-Release Tablets on Breathlessness in Patients with Idiopathic Pulmonary Fibrosis Experiencing Chronic Cough from the Phase 2b CORAL Trial

Poster Session: C103 The Next Frontier of Therapy in Pulmonary Fibrosis
Date & Time: May 19, 2:15 p.m. to 4:15 p.m. ET
Location: West F3 (Level II, OCCC West Concourse)
Presenter: Donald A. Mahler, MD

Final results from the presentations listed above will be presented at the ATS International Conference; Registration Details

About the Phase 2b CORAL Trial
The Phase 2b Cough Reduction in IPF with nalbuphine ER (CORAL) trial was a double-blind, randomized, placebo-controlled, parallel-arm trial evaluating three doses of nalbuphine ER (27 mg, 54 mg, and 108 mg twice daily) compared to placebo for the treatment of chronic cough in patients with IPF over a 6-week treatment period. 165 patients with IPF chronic cough were randomized 1:1:1:1 to one of three nalbuphine ER dose groups or placebo with an initial 2-week titration period to the target dose followed by 4 weeks of fixed dosing. The primary efficacy endpoint for the trial was the relative change in 24-hour cough frequency (coughs per hour), as determined by an objective cough monitor, for the modified intent-to-treat (mITT) population at the end of Week 6 versus Baseline for nalbuphine ER compared to placebo. The mITT population consisted of all patients who were randomized and received at least one dose of study drug or placebo.

About the Phase 2a RIVER Trial
The Phase 2a Refractory Chronic Cough Improvement Via Nalbuphine ER (RIVER) trial was a randomized, double-blind, placebo-controlled, two-treatment, two-period, crossover study designed to evaluate the efficacy, safety, and tolerability of nalbuphine ER for the treatment of patients with RCC. Each treatment period lasted 21 days, separated by a 21-day washout period. During the nalbuphine ER treatment period, patients were titrated with assessments at 27 mg twice daily (BID), 54 mg BID, and 108 mg BID for objective cough and other assessments at each dose. The primary endpoint of the trial was the mean change in 24-hour cough frequency, as determined by an objective cough monitor, for the full analysis set (FAS) population at Day 21. The FAS population included all patients who received at least one dose of study drug and have objective cough count data on both Baseline and Day 21 in at least one treatment period.

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-related 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 ~140,000 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.

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