Trevi Therapeutics Announces Multiple Late-Breaking Abstracts Accepted for Presentation at Upcoming Medical Conferences on Analysis of Oral Nalbuphine Extended Release

Late-breaker abstract accepted for oral presentation on the interim analysis of cough in patients with idiopathic pulmonary fibrosis (IPF) at the upcoming European Respiratory Society International Congress 2022, Barcelona, Spain, September 4-6

Late-breaker abstract accepted for oral presentation on topline data for the treatment of prurigo nodularis (PN) at upcoming 31st European Academy of Dermatology and Venereology Congress, Milan, Italy, September 7-10

NEW HAVEN, Conn., Aug. 24, 2022 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing an investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of prurigo nodularis (PN) and chronic cough in adults with idiopathic pulmonary fibrosis (IPF), today announced two late-breaking abstracts were accepted for presentation at upcoming fall medical conferences. The previously disclosed positive interim data from CANAL, a phase 2 trial for chronic cough in IPF, will be presented as an oral late-breaker abstract presentation at the European Respiratory Society (ERS) International Congress 2022 in Barcelona, Spain. The previously disclosed positive topline data from PRISM, a phase 2b/3 trial in PN, will be presented as an oral late-breaker abstract presentation at the 31st European Academy of Dermatology and Venereology (EADV) Congress in Milan, Italy.

Conference Details

ERS (European Respiratory Society) International Congress 2022 (September 4-6)

Session:	What is hot in interstitial lung diseases
Title:	An interim analysis of a phase 2 trial evaluating oral nalbuphine extended release for treating chronic cough in idiopathic pulmonary fibrosis
Location:	Barcelona, Spain
Presentation:	September 4, 2:50 PM CET
Presenter:	Toby Maher, MD, Professor of Medicine and Director of Interstitial Lung Disease at Keck School of Medicine, University of Southern California
Registration Details:	https://www.ersnet.org/congress-and-events/congress/

31st EADV (European Academy of Dermatology and Venereology) Congress (September 7-10)

Session:	D2T01.3: Late Breaking News
Title:	Oral Nalbuphine Extended-Release Is Effective in Severe Prurigo Nodularis–Associated Pruritus: Results From a Phase 2b/3, Double-Blind, Placebo-Controlled Study
Location:	Milan, Italy
Presentation:	September 9, 5:00 PM CEST
Presenter:	Sonja Ständer, MD, Professor of Dermatology and Neurodermatology at the University Hospital Münster
Registration Details:	https://eadvcongress2022.org/

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The CANAL (**C**ough **A**nd **NAL**buphine) trial is a Phase 2 double-blind, randomized, placebo-controlled, 2-treatment, 2-period crossover efficacy and safety study of nalbuphine ER for chronic cough in IPF. Statistically significant efficacy results from the interim analysis (N=26) were announced:

- The primary efficacy endpoint demonstrated a 77.3% reduction in daytime cough frequency from baseline with the use of nalbuphine ER compared to a 25.7% reduction with placebo, demonstrating a 52% placebo-adjusted reduction in the geometric mean percent change in the daytime cough frequency ($p<0.0001$).
- Expect to report efficacy and safety data on the full set of subjects in the third quarter of 2022.

The PRISM (**P**ruritus **R**elief through **I**tch-**S**cratch **M**odulation) trial is a Phase 2b/3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of nalbuphine ER in prurigo nodularis. As previously announced in the PRISM trial, results comparing subjects randomized to nalbuphine ER (n=168) or placebo (n=176) achieved the primary and all key secondary endpoints:

- 25% of nalbuphine ER subjects evaluated at week 14 met the primary endpoint of a 4-point reduction in the Worst Itch Numerical Rating Scale from baseline compared to 14% of placebo subjects ($p=0.0157$).
- Nalbuphine ER subjects experienced significantly greater improvements in ItchyQoL vs. placebo ($p=0.0002$) at week 14, which was statistically significant across each of the three domains (symptoms, functional limitations, and emotions). ItchyQoL is used to measure how pruritus impacts a subject's quality of life.
- 55% of nalbuphine ER subjects had at least a 1-category improvement in the 5-point scale in their Prurigo Activity Score (PAS) (pruriginous lesions with excoriations), vs. 38% on placebo ($p=0.006$) as evaluated at week 14.
- Nalbuphine ER subjects experienced significantly greater improvements in the PROMIS sleep disturbance short form 8a vs. placebo ($p=0.0002$) at week 14. The first assessment of PROMIS was made at week 6 of the trial and results at week 6 also demonstrated a statistically significant improvement.

The safety results of both trials were generally consistent with the known safety profile of nalbuphine ER from previous trials.

About Chronic Cough in Idiopathic Pulmonary Fibrosis

IPF is a serious, end of life disease where cough is one of the most significant symptoms. There are estimated to be 130,000 IPF patients in the US and more than 1 million patients ex-US, where up to 85% of these patients experience chronic cough. There are no approved therapies for the treatment of chronic cough in IPF, and the cough is often refractory to antitussive therapy. Patients with chronic cough in IPF can cough up to 1,500 times per day, leading to increased feelings of anxiety as it induces breathlessness. Coughing spells or episodes lead to significant fatigue, air hunger, peripheral oxygen desaturation, and some patients also experience cough-related urinary incontinence. The social impact of chronic cough in IPF further compounds limited exercise ability, reduced walking distance, and the need to use supplemental oxygen. The chronic cough in IPF may be an early clinical marker of disease activity, it can identify patients at high risk of progression, predict time to death or lung transplant, and may also contribute to enhanced activation of profibrotic mechanisms and disease worsening in IPF.

About Prurigo Nodularis

Prurigo nodularis is a chronic disease characterized by severe pruritus and the presence of nodules, lesions, and excoriations. Chronic pruritus is a key contributing cause of prurigo nodularis and manifests in an itch-scratch cycle, which is difficult to disrupt. There are no approved therapies for prurigo nodularis where a large unmet need exists due to its impact on patients' quality of life, function, and emotional well-being.

About Trevi Therapeutics, Inc.

Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of the investigational therapy Haduvio for the treatment of prurigo nodularis and chronic cough in adults with idiopathic pulmonary fibrosis. These conditions share a common pathophysiology that is mediated through opioid receptors in the central and peripheral nervous systems.

Founded in 2011, Trevi Therapeutics is headquartered in New Haven, CT.

About Haduvio

Haduvio, an investigational therapy, is an oral extended-release (ER) formulation of nalbuphine. Nalbuphine is a mixed κ-opioid receptor agonist and μ-opioid receptor antagonist that has been approved and marketed as an injectable for pain indications for more than 20 years in the United States and Europe. The κ- and μ-opioid receptors are known to be critical mediators of itch, cough and certain movement disorders. Nalbuphine's mechanism of action may also mitigate the risk of abuse associated with μ-opioid agonists because it antagonizes, or blocks, μ-opioid receptors. Parenteral nalbuphine is not currently scheduled as a controlled substance by the DEA in the United States or by regulatory authorities in most of Europe. Trevi intends to propose Haduvio as the trade name for nalbuphine ER. Nalbuphine ER has been granted Fast Track designation by the FDA for the treatment of itch in patients with prurigo nodularis. Its safety and efficacy have not been evaluated by any regulatory authority.

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 the expected timing of reporting top-line data from the full set of subjects' data from Trevi's Phase 2 CANAL trial of Haduvio in chronic cough in adults with IPF; Trevi's business plans and objectives, including future plans or expectations for Haduvio; expectations regarding Trevi's uses and 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 ongoing and planned clinical trials, including with respect to the timing of reporting top-line data from the Phase 2 CANAL trial; uncertainties regarding Trevi's ability to execute on its strategy; the risk that positive interim or top-line results from a clinical trial may not necessarily be predictive of the results of the completed trial or other future or ongoing clinical trials; potential regulatory developments in the United States and foreign countries; uncertainties regarding fast track designation and the effect such status could have on the regulatory review or approval process; uncertainties inherent in estimating Trevi's cash runway, future expenses and other financial results, including Trevi's ability to continue as a going concern, comply with its obligations under its loan facility and fund future operations; uncertainties regarding the scope, timing and severity of the COVID-19 pandemic, the impact of the COVID-19 pandemic on Trevi's clinical operations and actions taken in response to the pandemic; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended June 30, 2022 filed with the Securities and Exchange Commission and in subsequent filings 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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