Trevi Therapeutics Provides Clinical Trial Updates for Haduvio™

Restart of Phase 2 Clinical Trial of Haduvio for Chronic Cough in Patients with IPF

Phase 2b/3 PRISM Trial of Haduvio for Severe Pruritus in Patients with Prurigo Nodularis Reaches 50% Enrollment Milestone

NEW HAVEN, Conn., Oct. 21, 2020 (GLOBE NEWSWIRE) -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company focused on the development and commercialization of Haduvio™ (nalbuphine ER) to treat serious neurologically mediated conditions, today, announced updates to their ongoing clinical trials of Haduvio. Patient screening has resumed for the Phase 2 trial of Haduvio for chronic cough in patients with idiopathic pulmonary fibrosis (IPF), a trial that was paused due to IPF patients being an at-risk population for COVID-19. In addition, the Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with prurigo nodularis, randomized its 180th subject, officially reaching 50% enrollment.

Phase 2 trial of Haduvio for chronic cough in patients with idiopathic pulmonary fibrosis (IPF): The Phase 2 clinical trial is a randomized, double-blind, placebo controlled, two-treatment, two-period, crossover study designed to evaluate the efficacy, safety, tolerability and dosing of nalbuphine ER for chronic cough in patients with IPF that is being conducted in the United Kingdom (UK). The study is designed to enroll approximately 60 subjects with a goal to have 44 study completers. The primary endpoint for the study is the mean percent change in daytime cough frequency as measured by a cough monitor. The study will also examine various secondary endpoints.

Professor Toby Maher, based at the Royal Brompton Hospital and the lead investigator for this Phase 2 trial, said, “I am pleased to see Trevi’s trial for chronic cough in IPF patients restart screening after pausing due to the COVID-19 pandemic. IPF is a debilitating disease, with chronic cough being a significant contributor to a patient’s reduced quality of life. Nalbuphine ER is of particular interest for the clinical treatment of chronic cough due to the potential of its mixed agonist/antagonist mechanism of action.”

“The Company has worked with Dr. Maher to amend the protocol to require fewer in-person visits by the subjects as well as fewer procedures,” said Dr. Thomas Sciascia, Trevi’s Chief Medical Officer. “We believe this better protects the overall safety of these patients during the time of the pandemic.”

The amended protocol was recently approved by the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK and patient screening has restarted at certain sites in the UK. Additionally, Trevi is analyzing the possible addition of study sites in Germany to potentially accelerate enrollment and mitigate the COVID-related risks inherent to recruitment from a single-country.

Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with prurigo nodularis:
During October, the PRISM trial randomized its 180th subject into the study, reaching 50% enrollment of the expanded trial size following the sample size re-estimation completed in July. We expect to complete enrollment in the PRISM trial in the third quarter of 2021 and report top-line data in the fourth quarter of 2021.

“We are pleased with the continued progress of our clinical development programs in these two severe conditions,” said Jennifer L. Good, President and CEO of Trevi Therapeutics. “We have seen continued momentum in the enrollment in the PN trial and look forward to helping the remaining clinical sites for cough in IPF get restarted.”

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of Haduvio to treat serious neurologically mediated conditions. Trevi is currently developing Haduvio for the treatment of chronic pruritus, chronic cough in patients with idiopathic pulmonary fibrosis (IPF) and levodopa-induced dyskinesia (LID) in patients with Parkinson’s disease. These conditions share a common pathophysiology that is mediated through opioid receptors in the central and peripheral nervous systems. Trevi is currently conducting a Phase 2b/3 clinical trial of Haduvio, referred to as the PRISM trial, in patients with severe pruritus associated with prurigo nodularis.

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

About HADUVIO

Haduvio is an oral extended release 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 also mitigates the risk of abuse associated with μ-opioid agonists because it antagonizes, or blocks, μ-opioid receptors. Nalbuphine is currently the only opioid approved for marketing that is not classified as a controlled substance in the United States and most of Europe. Trevi intends to propose Haduvio as the trade name for the nalbuphine ER investigational product. Haduvio is an investigational drug product and its safety and efficacy have not been fully 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 impact of the COVID-19 pandemic on our clinical trials, business and operations, the expected timing of enrollment and for reporting top-line data from, Trevi's Phase 2b/3 PRISM trial of Haduvio in patients with prurigo nodularis; the expected timing of milestones for the Company's other ongoing and planned clinical trials; Trevi's business plans and objectives, including future plans or expectations for Trevi's product candidates and 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; 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; uncertainties regarding Trevi's ability to execute on its strategy, including to enroll patients in the anticipated timeframes; the risk that positive results from a clinical trial may not necessarily be predictive of the results of future or ongoing clinical trials; potential regulatory developments in the United States and foreign countries; uncertainties inherent in estimating our cash runway, future expenses and other financial results; as well as other risks and uncertainties set forth in the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2020 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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