Trevi Therapeutics Announces Positive Outcome of the Sample Size Re-Estimation Analysis in PRISM Trial for Severe Pruritus in Patients With Prurigo Nodularis

Independent Data Monitoring Committee Recommends Continuation of PRISM Trial with Expansion to 360 Subjects per the Adaptive Design

Enrollment Expected to be Complete by Third Quarter 2021

Introducing HADUVIO™ as Proposed Trade Name for Nalbuphine ER

NEW HAVEN, Conn., July 13, 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 the completion of the pre-specified sample size re-estimation (SSRE) analysis for the ongoing PRISM Phase 2b/3 trial of Haduvio for severe pruritus in patients with prurigo nodularis (PN).

Based on the SSRE analysis the independent Data Monitoring Committee (DMC) recommended that the PRISM trial should continue and that the trial size should increase from an initial enrollment target of 240 to 360 subjects which maintains the statistical power for the primary endpoint. The DMC's recommendation was based on a pre-specified interim conditional power assessment conducted after approximately 45% of the initial targeted number of patients were evaluable for the primary endpoint of the trial. Based on the DMC's recommendation, the Company plans to increase the size of the trial to 360 subjects.

"Severe pruritus in prurigo nodularis is a very serious and difficult-to-treat condition. We are pleased with the re-estimation results midway through the trial which inform the sample size and further reinforces our view that Haduvio may be an effective treatment option for patients with PN," said Jennifer L. Good, President and CEO of Trevi Therapeutics. "Enrollment in the PRISM trial has been picking up nicely since the removal of most COVID-19 screening and enrollment restrictions. We have increased the number of active sites to more than 60 globally and approximately 140 subjects have enrolled in the study. Based on the increased sample size, and considering COVID-19 related restrictions, we expect to complete enrollment in the third quarter of 2021 and report top-line data in the fourth quarter of 2021."

PRISM Phase 2b/3 Trial Design
The PRISM trial is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Haduvio for severe pruritus in patients with prurigo nodularis. In this trial, subjects are randomized equally across two treatment groups (Haduvio 162 mg or placebo, twice daily including an initial 2-week blinded titration period). The primary endpoint of the trial is the proportion of patients achieving a greater than or equal to 4-point improvement in the weekly mean Worst Itch Numerical Rating Scale (WI-NRS) score at Week 14, after which all participants rollover to an open-label extension.

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 (PN).

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 and will therefore use that name in Company materials going forward. 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; Trevi’s business plans and objectives, including future plans or expectations for Trevi’s product candidates; 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; 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 future expenses, capital requirements and other financial results; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended March 31, 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.

Investor Contact
Chris Seiter, Chief Financial Officer
Trevi Therapeutics, Inc.
chris.seiter@trevitherapeutics.com
203-304-2499

Media Contact
Rosalia Scampoli
rscampoli@marketcompr.com
914-815-1465
