Trevi Therapeutics Announces Clinical Trial Updates for Lead Indications

Phase 2 CANAL (Chronic Cough in IPF) Planned Interim Statistical Update 1Q 2022, with Top-Line Data 1H 2022
Phase 2b/3 PRISM (Chronic Pruritus in PN) Enrollment to End January 31, 2022, with Top-Line Data 1H 2022

NEW HAVEN, Conn., Jan. 5, 2022 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI) is a clinical-stage biopharmaceutical company developing an investigational therapy Haduvio™ (nalbuphine ER) to treat serious neurologically mediated conditions. Today, Trevi announced that it expects to perform an interim statistical update in the first quarter of 2022 for its ongoing Phase 2 CANAL trial of Haduvio in patients suffering from chronic cough due to idiopathic pulmonary fibrosis (IPF). Trevi also announced that it expects to end enrollment in its Phase 2b/3 PRISM trial for pruritus associated with prurigo nodularis (PN) by January 31, 2022.

Trevi announces a planned interim statistical update for CANAL 1Q 2022 and enrollment end date for PRISM Jan. 31, 2022

Trevi intends to conduct the interim statistical update for the CANAL trial based on a conditional power assessment. The CANAL trial is a randomized, double-blind, placebo controlled, two-treatment, two-period, crossover study. An independent statistician will review the pre-planned analysis on the primary endpoint of change in daytime cough frequency for oral nalbuphine ER compared to placebo. The information from the statistical update will be used to determine whether proof-of-concept can be established prior to the full enrollment of the study. The Company expects to complete the statistical update in the 1Q 2022.

Trevi continues progress in its PRISM Ph2b/3 trial in pruritus with prurigo nodularis and expects to end enrollment by the end of January. The Company continues to expect top-line data from the 14-week blinded portion of the trial in the 1H 2022.

"We are looking forward to the planned interim statistical update for the CANAL trial and the end of enrollment for the PRISM trial. Both clinical trials are incredibly important to patients and providers as there are currently no therapies approved for either of these indications," said Dr. Bill Forbes, Chief Development Officer. "Up to 85% of IPF patients experience chronic cough. IPF patients consider cough one of their most bothersome symptoms, and one that has a significant impact on their quality of life. We are excited to include this interim statistical update in our CANAL trial with the goal of potentially accelerating further development in this area."

"The majority of IPF patients suffer from chronic cough. For many people, it involves a series of coughing fits throughout the day, leaving them feeling breathless and physically tired. IPF patients often have to withdraw from social activities and give up work, due to their cough, which increases their isolation. We urgently need new treatments for this debilitating condition," said Steve Jones, Chair of Trustees at Action for Pulmonary Fibrosis, UK. "We do not currently have effective treatments for cough associated with IPF," said Liam Galvin, CEO of the European Pulmonary Fibrosis Federation (EU-IPFF). "There is an urgent need for more research into cough related to IPF to help improve overall quality of life of those diagnosed with this life-threatening disease. Patient advocacy has a key role to play in strengthening the IPF patient's voice and raising awareness in an area of high unmet need."

Upcoming Meetings
The Company plans to attend the following upcoming conferences:

- 11th Annual LifeSci Partners Corporate Access Event, January 5-7, 2022
- Dermatology Summit, January 7, 2022
- H.C. Wainwright BioConnect Virtual Conference, January 10-13, 2022
- Biotech Showcase, January 10-12 and 17-19, 2022
- Winter Clinical Dermatology Conference, January 14-19, 2022
- Maui Derm for Dermatologists, January 24-28, 2022

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of the investigational therapy Haduvio to treat serious neurologically mediated conditions. Trevi is conducting a Phase 2b/3 clinical trial of Haduvio for the treatment of chronic pruritus associated with prurigo nodularis (PN) and a Phase 2 trial for chronic cough in patients with idiopathic pulmonary fibrosis (IPF). Trevi is also developing Haduvio for the treatment of 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.

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 classified 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. Haduvio is an investigational therapy that has been granted Fast Track designation by the FDA for the proposed indication of reduction of moderate to severe pruritus 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 impact of the COVID-19 pandemic on Trevi's 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 PN and for the interim analysis and top-line data from the Phase 2 CANAL trial of Haduvio for chronic cough in patients with IPF; Trevi's business plans and objectives, including future plans or expectations for Trevi's product candidates; 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 enrollment and the timing of the planned interim analysis and of top-line data; 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 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 and its obligations under its loan facility; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended September 30, 2021 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
Katie McManus
Trevi Therapeutics, Inc.
203-304-2499
k.mcmanus@trevitherapeutics.com

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

SOURCE Trevi Therapeutics, Inc.
