Trevi Therapeutics Completes Enrollment for Phase 2b/3 PRISM Study in Chronic Pruritus in PN

Top-Line Data Expected 2Q 2022

NEW HAVEN, Conn., Feb. 1, 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 has completed enrollment in its Phase 2b/3 PRISM trial for pruritus associated with prurigo nodularis (PN) and expects to report top-line data in the second quarter of 2022.

Trevi completes enrollment in Ph2b/3 PRISM Study in chronic pruritus in prurigo nodularis, expecting top-line data 2Q 22

"We are pleased to have completed enrollment in our Phase 2b/3 PRISM trial and look forward to reporting top-line data in the second quarter of this year," said Jennifer Good, President and CEO. "This is an important milestone in the development of Haduvio which is the lead oral compound in clinical development for pruritus in PN and which we believe may offer an important treatment option to these seriously impacted patients. By targeting the pruritus associated with prurigo nodularis, Haduvio is designed to break the itch-scratch cycle which has a significant impact on patients' quality of life. We look forward to seeing these results and advancing the development of Haduvio to address the unmet need of patients with pruritus across conditions."

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 PN. In the trial, subjects are randomized equally across two treatment groups (oral 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 subjects 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 compared to baseline. The planned enrollment for the trial was approximately 360 subjects.

The Company previously announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation of nalbuphine ER for the proposed indication of reduction of moderate to severe pruritus in patients with PN. Fast Track designation is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously.

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. 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 reporting top-line data from Trevi's Phase 2b/3 PRISM trial of Haduvio in patients with PN; 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 the timing of the planned interim analysis for the CANAL trial and of top-line data from both the PRISM and CANAL 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 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.

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