Trevi Therapeutics to Participate at 21st Annual Needham Virtual Healthcare Conference

Fireside chat will be held on Tuesday, April 12, 2022, from 8:00 a.m. to 8:40 a.m. EDT

NEW HAVEN, Conn., April 5, 2022 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI) is a clinical-stage biopharmaceutical company developing an investigational oral therapy Haduvio™ (nalbuphine ER) for pruritus in prurigo nodularis (PN) and chronic cough in idiopathic pulmonary fibrosis (IPF). Today, Trevi announced that Jennifer Good, President and Chief Executive Officer, along with Dr. Bill Forbes, Chief Development Officer, will participate in a fireside chat at the 21st Annual Needham Virtual Healthcare Conference on Tuesday, April 12, 2022, at 8:00 a.m. ET.

A live webcast of the fireside chat will be accessible from the 'Investors & News' section on the Company's website at www.TreviTherapeutics.com. An archived replay of the webcast will also be available for 30 days on the Company's website following the event.

About CANAL

Interim analysis results from the Phase 2 Cough And NALbuphine (CANAL) trial were statistically significant on the primary efficacy endpoint with a 77% reduction in daytime cough frequency from study baseline for Haduvio, demonstrating a 52% placebo-adjusted reduction in the geometric mean percent change ($p<0.0001$) (N=26). The secondary endpoints supported the benefit seen in the primary endpoint. Based on the strength and consistency of the efficacy data, Trevi stopped recruitment and expects top-line data for the full set of subjects in the third quarter of 2022. This interim analysis was specifically to assess efficacy. There have been no reported deaths in the CANAL trial and 1 reported Serious Adverse Event (pneumonia) which was not considered treatment related. The CANAL trial is a double-blind, randomized, placebo-controlled, 2-treatment, 2-period crossover efficacy and safety study of nalbuphine ER for chronic cough in patients with IPF taking place in the United Kingdom. The study consists of 2 treatment periods of 3 weeks, with a washout period of 2 weeks after each treatment period. The primary efficacy endpoint is to evaluate the effect of nalbuphine ER tablets on the mean daytime cough frequency at day 22 compared to placebo as measured by an objective cough monitor. More information about the CANAL trial is available at www.clinicaltrials.gov: NCT04030026

About PRISM

The Phase 2b/3 Pruritus Relief through Itch Scratch Modulation (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. Top-line data is expected in the second quarter of 2022. More information about the PRISM trial is available at www.clinicaltrials.gov: NCT03497975

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). 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 expected timing of reporting top-line data from Trevi's Phase 2b/3 PRISM trial of Haduvio in subjects with PN and 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 IPF subjects with chronic cough; 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 reporting top-line data from both Trevi's Phase 2b/3 PRISM trial and 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 annual report on Form 10-K for the year ended December 31, 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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