Trevi Therapeutics Announces Results from Phase 2b/3 PRISM Open-Label Extension Study of Haduvio™ in Prurigo Nodularis

Continued reduction in WI-NRS observed among participants who remained in the study through 52 weeks of treatment

Safety data over 52 weeks: treatment was well tolerated and consistent with 14-week blinded safety data

Preliminary analyses presented at the European Academy of Dermatology & Venereology (EADV) Congress 2023

NEW HAVEN, Conn., Oct. 13, 2023 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for difficult to treat patients with chronic cough in idiopathic pulmonary fibrosis (IPF), other chronic cough indications and prurigo nodularis, today announced the 52-week results from its phase 2b/3 PRISM open-label extension (OLE) study of Haduvio for the treatment of prurigo nodularis. The data was presented by Professor Elke Weisshaar on October 13th at the European Academy of Dermatology & Venereology (EADV) Congress 2023 in Berlin, Germany. The slides from the presentation will be available for 30 days on the Company's website.

"We are pleased with the results from our preliminary analyses of our OLE data supporting the safety profile of nalbuphine ER up to 52 weeks which were presented at EADV today," said Jennifer Good, President and CEO of Trevi Therapeutics. "The long-term data also supports the continued effectiveness of Haduvio in reducing itch over 52 weeks for the participants who remained in the study. We are preparing for an end of phase 2 meeting with the FDA to discuss next steps in development for this program."

The phase 2b/3 PRISM (**P**ruritus **R**elief through **I**tch-**S**cratch **M**odulation) trial was a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of nalbuphine ER in prurigo nodularis. Following the completion of the initial 14-week portion of the trial, subjects were eligible to roll into an additional 38-week open label extension period during which all participants received Haduvio 162mg twice a day (BID). Post hoc analyses demonstrated continued reduction in mean WI-NRS for those participants who remained on Haduvio through 52 weeks.

Adverse Events Reported During 38-Week Open-Label Period
151 subjects completed the open-label extension, adding to the safety database for Haduvio. The safety data were generally consistent with the safety profile of Haduvio observed in the 14-week portion of PRISM and previous trials of Haduvio. Adverse events reported with a frequency greater than 5% in the 38-week open-label period included nausea, dizziness, vomiting, fatigue, and somnolence. Study discontinuation due to adverse events occurred in 13% of subjects during the open-label period, and serious adverse events were reported for 13 subjects, although only 2 of these events were considered potentially treatment related.

About PRISM
The Phase 2b/3 Pruritus Relief through Itch Scratch-Modulation (PRISM) trial was a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Haduvio in prurigo nodularis. In the trial, participants were 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 was the proportion of participants 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. Participants that completed week 14 were eligible to roll into an additional 38-week open label extension trial. 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 developing the investigational therapy Haduvio™ (oral nalbuphine ER) for difficult to treat patients with chronic cough in idiopathic pulmonary fibrosis (IPF), other chronic cough indications, and prurigo nodularis. Haduvio is a dual κ-opioid receptor agonist and μ-opioid receptor antagonist that works both centrally as well as peripherally in the lungs.

Parenteral nalbuphine is not scheduled by the US Drug Enforcement Agency. Trevi intends to propose Haduvio as the trade name for oral nalbuphine ER. Its safety and efficacy have not been evaluated by any regulatory

authority.

For more information, visit www.TreviTherapeutics.com and follow Trevi on Twitter and LinkedIn.

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 Trevi's business plans and objectives, including future plans or expectations for Haduvio and plans and timing with respect to future clinical trials, 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; the risk that positive data from a clinical trial may not necessarily be predictive of the results of future clinical trials in the same or a different indication; uncertainties regarding Trevi's ability to execute on its strategy; uncertainties with respect to regulatory authorities' views as to the data from Trevi's clinical trials and next steps in the development path for Haduvio in the United States and foreign countries, including Trevi's ability to submit and get clearance of an IND and other regulatory filings on a timely basis; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended June 30, 2023 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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