Trevi Therapeutics Provides Update on Haduvio's Clinical Development Program

October 3, 2024

Phase 2b CORAL trial in idiopathic pulmonary fibrosis (IPF) chronic cough reaches 50% enrollment milestone; sample size re-estimation results expected in December 2024

Human Abuse Potential (HAP) study dosing complete; topline results expected in December 2024

NEW HAVEN, Conn., Oct. 3, 2024 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC), today provided updates on its clinical development programs.

"We are excited to report these important clinical milestones that mark an impending data-rich period for Trevi's Haduvio," said Jennifer Good, President and CEO of Trevi Therapeutics. "Chronic cough in IPF is one of the most difficult-to-treat cough conditions where antifibrotics have not shown a benefit. We believe the centrally and peripherally acting mechanism of Haduvio uniquely positions it to work throughout the cough reflex arc and potentially offer relief for this important unmet need in IPF."

Clinical Updates

- The Phase 2b CORAL trial for the treatment of chronic cough in patients with IPF has enrolled 50% of the targeted study enrollment, which is the number of patients needed for the pre-specified sample size re-estimation (SSRE). The SSRE will be performed once the last of these patients complete the six weeks of treatment. The outcome of the SSRE result is expected in December 2024. The three potential SSRE outcomes are: maintain current sample size (N=160), upsize within a pre-specified range, or evaluate for futility. Assuming no adjustments are made to the sample size, topline results are expected in the first half of 2025.
- The Human Abuse Potential (HAP) study completed dosing. Topline results are expected in December 2024.
- The Phase 2a RIVER trial for the treatment of RCC has enrolled the planned sample size but remains open to allow for additional enrollment in both arms to approximate the stratification targets. Topline results are now expected in the first quarter of 2025.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio ™ (oral nalbuphine ER) for the treatment of chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC). Haduvio is an extended-release (ER) dual κ-opioid receptor agonist and μ-opioid receptor antagonist that works both centrally in the brain as well as peripherally in the lungs and has the potential for a synergistic antitussive effect to treat chronic cough. Parenteral nalbuphine is not scheduled by the U.S. Drug Enforcement Agency.

The impact of chronic cough is significant and often leads to a decline in patients' social, physical, and psychological quality of life. In IPF, chronic cough may lead to worsening disease and may be associated with a higher risk of progression, death, or need for lung transplant. There are no approved therapies for the treatment of chronic cough in IPF and current treatment options provide minimal benefit to patients. Chronic cough affects up to 10% of the adult population, and Haduvio's expansion into RCC has the potential to reach patients suffering from moderate to severe refractory chronic cough. There are also no approved therapies for RCC in the U.S.

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 X (formerly 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 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 and timing of Trevi's product candidate development activities, including its ongoing clinical trials; the risk that positive data from a clinical trial may not necessarily be predictive of the results of later 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, uncertainties inherent in estimating Trevi's cash runway, future expenses and other financial results, including Trevi's ability to fund future operations, including clinical trials, as well as other risks and uncertainties set forth in

the quarterly report on Form 10-Q for the quarter ended June 30, 2024 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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