Trevi Therapeutics Provides Business Updates

NEW HAVEN, Conn., Jan. 4, 2024 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for patients with chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC), today announced a preview of business updates. Management will be attending the 13th Annual LifeSci Partners Corporate Access Event in San Francisco from January 8-10 and will be available to discuss updates. This event takes place during the week of the annual J.P. Morgan Health Care Conference.

Trevi to attend 13th Annual LifeSci Partners Corporate Access Event and provides business updates

"Our team is very excited about Trevi's outlook for 2024 having initiated two clinical trials in chronic cough and the Human Abuse Potential study late in 2023," said Jennifer Good, President and CEO of Trevi Therapeutics. "We look forward to advancing the development of Haduvio through both our Phase 2b CORAL dose ranging trial for chronic cough in IPF and our Phase 2a RIVER proof-of-concept trial in refractory chronic cough, as well as completing the Human Abuse Potential study. We believe Haduvio's ability to work both centrally in the brain and peripherally in the lungs has the potential for a synergistic antitussive effect to treat chronic cough that could enable use among patients with both moderate and severe cough frequencies. We look forward to a data-rich year as we progress through this next critical stage of development."

Key Business Updates

- The Phase 2b CORAL trial in IPF patients with chronic cough has regulatory approval in 8 of the 10 expected countries. The trial includes a sample size re-estimation (SSRE) which is expected to occur in the second half of 2024 after approximately 50% of the patients in the trial are evaluable for the primary endpoint. Full enrollment in the trial is expected this year and topline results are expected in the first half of 2025, assuming no adjustments are made to the sample size as a result of the SSRE.
- The Phase 2a RIVER trial in RCC patients has been initiated and the first patient was randomized. Topline data from the trial is expected in the second half of 2024.
- The Human Abuse Potential study is active and dosing is expected to begin in January 2024, with topline data expected in the second half of 2024.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for patients with chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC). Trevi also is evaluating Haduvio for prurigo nodularis. Haduvio is a 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.

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 relief to patients. RCC 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 chronic cough. There are also no approved therapies for RCC in the US.

Parenteral nalbuphine is not scheduled by the U.S. 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 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, cost and timing of Trevi's product candidate development activities and ongoing and planned clinical trials; the risk that 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, including Trevi's ability to submit and get clearance of an IND and other regulatory filings on a timely basis; 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 September 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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