Trevi Therapeutics Provides Business Update Ahead of Upcoming Conferences

NEW HAVEN, Conn., Jan. 5, 2023 /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 adults with idiopathic pulmonary fibrosis (IPF) and other chronic cough indications, and for the treatment of prurigo nodularis, today announced business updates.

"I am proud of the clinical and financial progress we have made over the past year, positioning Trevi for an exciting year ahead. We are focused on progressing the clinical development of Haduvio in chronic cough in IPF while also expanding into refractory chronic cough," said Jennifer Good, President and CEO of Trevi Therapeutics. "We have also initiated a human abuse liability study and are preparing for an End-Of-Phase 2 meeting on our prurigo nodularis program."

Key Business Updates

- The Company continues to work with the U.S. Food and Drug Administration (FDA) as well as other European regulatory authorities, to align on the next steps in the development of Haduvio for the treatment of chronic cough in IPF.
- The Company anticipates conducting the following clinical studies in 2023:
  - A Phase 2 dose-ranging study of Haduvio for the treatment of chronic cough in IPF is expected to initiate in the second quarter of 2023. The Company expects that the study will evaluate three active doses and placebo with the goal of informing the potential Phase 3 program.
  - A Phase 1b respiratory physiology study of Haduvio in IPF patients that is designed to confirm the population to be included in the potential Phase 3 program.
  - A Phase 2 proof-of-concept study of Haduvio for the treatment of refractory chronic cough that is expected to initiate in the third quarter of 2023.
  - Complete the open-label extension of its Phase 2b/3 PRISM trial for the treatment of prurigo nodularis in the first quarter of 2023 and request an End-of-Phase 2 meeting with the FDA for mid-2023.
  - Initiation of dosing has begun in the Company's human abuse liability study, which is expected to be completed by the end of 2023. This is a randomized, double-blind, active and placebo-controlled 5-way crossover study to determine the abuse potential of oral nalbuphine relative to butorphanol.

Upcoming Meetings
The Company plans to participate in the following upcoming conferences and events:

- January 10, 2023: Presentation at Biotech Showcase 2023, 3:00 p.m. PT
- January 9-11, 2023: 12th Annual LifeSci Partners Corporate Access Event being held in San Francisco, CA

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational oral therapy Haduvio™ (nalbuphine ER) for the treatment of chronic cough in adults with IPF, other chronic cough indications, and for the treatment of prurigo nodularis. The Company reported statistically significant results from the Phase 2 CANAL trial of Haduvio for the treatment of chronic cough in adults with IPF. Based on this positive data, Trevi plans to focus future clinical development on chronic cough conditions, including IPF, refractory chronic cough, and interstitial lung diseases (ILDs).

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

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 centrally and peripherally active and known to be critical mediators of cough and itch. 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 scheduled 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. 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 Trevi's business plans and objectives, including future plans or expectations for Haduvio and plans 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; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended September 30, 2022 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.

Investor Contact
Katie McManus
Trevi Therapeutics, Inc.
203-304-2499
k.mcmanus@trevitherapeutics.com

Media Contact
Rosalia Scampoli
914-815-1465
rscampoli@marketcompr.com

SOURCE Trevi Therapeutics, Inc.
