Trevi Therapeutics Appoints Pharma Industry Veteran as Chief Medical Officer

David Clark, MD, MRCP, will lead the continued development of Haduvio™

NEW HAVEN, Conn., Nov. 14, 2022 /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 the appointment of David Clark, MD, MRCP, as Chief Medical Officer (CMO). Dr. Clark will join Trevi's executive team and be responsible for the strategy and execution of Haduvio's clinical programs.

"I am pleased to welcome David to our executive leadership team," said Jennifer Good, President and CEO of Trevi Therapeutics. "David brings his respiratory background to Trevi through his medical training and drug development experience. In addition, we believe his strong track record as a biotech CMO and successful delivery of Phase 3 programs will enable David to play a key role as we progress the development of Haduvio in our targeted indications."

Dr. Clark joins Trevi with over 25 years of global clinical development experience in big pharma and biotech. Most recently, Dr. Clark served as Chief Medical Officer at Allena Pharmaceuticals, leading the Company's clinical development, regulatory and medical affairs teams. Prior to that, he served as Chief Medical Officer for various companies, including Aldeyra Therapeutics, Wilson Therapeutics, and NormOxys. As Chief Medical Officer, Dr. Clark has strategized and supported teams from clinical translation through Phase 3. He has also held senior leadership positions at TransTech Pharma, Pfizer, SmithKline Beecham, and GlaxoSmithKline. Dr. Clark holds a Bachelor of Medicine and Surgery (MD) from the University of Edinburgh Medical School, and a Membership of the Royal College of Physicians (MRCP). Dr. Clark also completed a research fellowship in respiratory medicine in the United Kingdom.

"Idiopathic pulmonary fibrosis is a very debilitating disease for patients in which cough plays a central role," said Dr. Clark. "I was impressed with the results from the Phase 2 CANAL trial and believe Haduvio's centrally acting mechanism has the potential to significantly impact this disease. I look forward to progressing Haduvio through development for the treatment of chronic cough in adults with IPF, as well as initiating development work in other serious chronic cough conditions."

Dr. Thomas Sciascia, MD, the co-founder of Trevi Therapeutics, previously served as Trevi's Chief Medical Officer and will be transitioning to Chief Science Officer. His background as a board-certified neurologist and his experience with the development of Haduvio to date provides a deep understanding of Haduvio's mechanism. Dr. Sciascia's extensive knowledge of Haduvio will be applied to strengthen the continued exploration of Haduvio in serious chronic cough conditions.

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 idiopathic pulmonary fibrosis (IPF) and other chronic cough indications, and for the treatment of prurigo nodularis. The Company has successfully completed a Phase 2 CANAL trial of Haduvio for the treatment of chronic cough in adults with idiopathic pulmonary fibrosis (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; 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; 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 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.
