Trevi Therapeutics Announces Appointment of James V. Cassella, Ph.D., as Chief Development Officer

September 30, 2024

NEW HAVEN, Conn., Sept. 30, 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 announced the appointment of James V. Cassella, Ph.D., as Chief Development Officer (CDO).

"I am delighted to welcome Jim, who has been a member of our Board of Directors for the past four years, to our executive management team as Chief Development Officer," said Jennifer Good, President and CEO of Trevi Therapeutics. "Our team is planning for the pivotal development program in IPF, the advancement in refractory chronic cough, and preparing for a regulatory submission of Haduvio. Jim will play an integral role in progressing Haduvio by utilizing his broad drug development experience and his proven hands-on leadership of scientific and regulatory teams through drug approvals. In particular, his extensive experience and execution in central nervous system (CNS) drug development together with his long-standing knowledge of Haduvio as a member of our board of directors, positions him to make an immediate impact at this important time for the Company."

"I am very excited to join the team at Trevi in a direct leadership role as I see the great potential that Haduvio's central and peripheral mechanism could have on treating patients suffering from chronic cough conditions," said Dr. Cassella. "It is a very important time at Trevi with the upcoming data read-outs and I look forward to leveraging my late-stage CNS drug development and regulatory experience to advance Haduvio through to approval."

Dr. Cassella has over 35 years of experience working in innovative publicly traded drug and product development companies with a specific focus on CNS therapies. Prior to joining Trevi as CDO, Dr. Cassella served as CDO for Concert Pharmaceuticals (acquired by Sun Pharma in 2023) where he spearheaded the development activities leading to the successful US FDA approval of the autoimmune JAK inhibitor, Leqselvi™. At Concert Pharmaceuticals, he was a key member of the Executive Team and the corporate transaction team leading to its $576 million Company acquisition by Sun Pharmaceutical Industries. Prior to joining Concert, Dr. Cassella was Executive Vice President, Research and Development and Chief Scientific Officer at Alexza Pharmaceuticals from 2004-2015, where he was responsible for the US and European approval of the CNS drug, Adasuve™. He held other various management positions, including Senior Vice President of Clinical Research and Development at Neurogen Corporation, an innovative CNS-focused biotechnology company, and was an Assistant Professor of Neuroscience at Oberlin College. Dr. Cassella received a Ph.D. in Physiological Psychology from Dartmouth College, completed a postdoctoral fellowship in the Department of Psychiatry at the Yale School of Medicine and received a B.A. in Psychology from the University of New Haven.

Dr. Cassella will replace Dr. David Clark, who has stepped down as Chief Medical Officer to help with the care of an immediate family member but will continue to consult for the Company. "We want to thank David for his contributions at Trevi and wish him and his family the best," said Good.

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 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. 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, expectations regarding Trevi's uses and sufficiency of capital, 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 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,, 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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