Trevi Therapeutics Announces the Hiring of Key Talent

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Expands Management Team to Support Clinical Development and Commercial Strategy of Haduvio™ in Multiple Late Stage Programs

NEW HAVEN, Conn., Oct. 13, 2020 (GLOBE NEWSWIRE) -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company focused on the development and commercialization of Haduvio™ (nalbuphine ER) to treat serious neurologically mediated conditions, today announced the appointment of Shashank Rohatagi, Ph.D., as Vice President, Pharmacology and Clinical Pharmacokinetics, Farrell Simon, Pharm.D., as Vice President, Head of U.S. Marketing, and Katherine S. Takaki, Ph.D., as Vice President, Global Regulatory Affairs. Dr. Rohatagi will be responsible for managing the supportive studies required to seek regulatory approvals as well as all CMC-related activities, and joins Trevi after senior roles at Metrum Research, Otsuka Pharmaceuticals and Daiichi Sankyo. Dr. Simon will lead the development and implementation of the commercial strategy for Haduvio, and joins Trevi from Pfizer. Dr. Takaki will oversee Trevi's global regulatory strategies including interactions with key regulatory authorities and leading any registration efforts for Haduvio, and joins the Company after working at Iterum Therapeutics and Bristol Myers Squibb.

"We are pleased to welcome Shashank, Farrell, and Kathy to our management team as we move forward with Haduvio," said Jennifer L. Good, President and Chief Executive Officer. "Their extensive backgrounds in various areas of the biopharmaceutical industry should be invaluable to the success of Trevi as we continue to advance Haduvio. We look forward to their insight as we work towards providing treatment to those suffering from serious conditions, such as chronic pruritus in patients with prurigo nodularis and chronic cough in idiopathic pulmonary fibrosis which currently have no approved therapies."

Dr. Rohatagi brings his diverse experience in the pharmaceutical industry and drug development to the Trevi team. As Senior Principal Scientist for Clinical Pharmacology at Metrum Research Group, he was responsible for providing strategic and operational support for clinical pharmacology and regulatory issues across therapeutic areas for various stages of drug development. Prior to that, Dr. Rohatagi was Vice President of Data Sciences at Otsuka managing the group that supported data analytics for all phases of development and regulatory submissions. Dr. Rohatagi holds a Ph.D. from the University of Florida in Pharmacokinetics/Pharmacodynamics and an M.B.A from St. Joseph's University.

Dr. Simon has a diverse set of experiences he brings to Trevi to develop and execute commercialization plans for Haduvio. His career spans both U.S. and global roles, where he has developed and implemented numerous marketing and sales campaigns to increase internal and external engagement. He is an experienced general manager who has successfully led operating plans for brands of varying size and worked across the lifecycle of products from in-line brands to early commercial development assets. Prior to joining Trevi, Dr. Simon most recently served as Chief of Staff to the Group President of Biopharma at Pfizer and was a member of the leadership team. In this role he led operations across seven innovative business units, as well as led pan-business unit strategic initiatives. He began his career at Procter & Gamble and holds both an M.B.A. and a Pharm.D. from the University of Florida.

Dr. Takaki joins Trevi with extensive pharmaceutical industry experience in regulatory strategy, global project and team management, and drug discovery. Before becoming part of Trevi, she served as Vice President, Global Regulatory Affairs at Iterum Therapeutics where she helped build out the regulatory group to support the company's regulatory strategy and operations. Prior to that, Dr. Takaki held leadership positions at Bristol Myers Squibb supporting multiple therapeutic areas. She was the global project manager for the team that developed Baraclude for the treatment of hepatitis B and launched it in markets worldwide. Her most recent role at Bristol Myers was Group Director, Head of Regulatory Strategy Marketed Products. She holds a Ph.D. in Organic Chemistry from the Massachusetts Institute of Technology and a B.S. in Chemistry from the University of Hawaii at Manoa.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of Haduvio to treat serious neurologically mediated conditions. Trevi is currently developing Haduvio for the treatment of chronic pruritus, chronic cough in patients with idiopathic pulmonary fibrosis (IPF) and levodopa-induced dyskinesia (LID) in patients with Parkinson's disease. These conditions share a common pathophysiology that is mediated through opioid receptors in the central and peripheral nervous systems. Trevi is currently conducting a Phase 2b/3 clinical trial of Haduvio, referred to as the PRISM trial, in patients with severe pruritus associated with prurigo nodularis.

Founded in 2011, Trevi Therapeutics is headquartered in New Haven, CT.

About HADUVIO
Haduvio is an oral extended release 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 known to be critical mediators of itch, cough and certain movement disorders. Nalbuphine's mechanism of action also mitigates the risk of abuse associated with μ-opioid agonists because it antagonizes, or blocks, μ-opioid receptors. Nalbuphine is currently the only opioid approved for marketing that is not classified as a controlled substance in the United States and most of Europe. Trevi intends to propose Haduvio as the trade name for the nalbuphine ER investigational product. Haduvio is an investigational drug product and its safety and efficacy have not been fully 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, Trevi's business plans and objectives,

including future plans or expectations for Trevi's product candidates and expectations regarding potential regulatory submissions; 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; 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; uncertainties regarding Trevi's ability to execute on its strategy; the risk that positive results from a clinical trial may not necessarily be predictive of the results of future or ongoing clinical trials; potential regulatory developments in the United States and foreign countries; uncertainties inherent in estimating our cash runway, future expenses and other financial results; as well as other risks and uncertainties set forth in the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2020 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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