Trevi Therapeutics Announces Notice of Allowance for U.S. Patent Application Covering Use of Haduvio™ (nalbuphine ER) for the Treatment of Chronic Cough in Idiopathic Pulmonary Fibrosis

NEW HAVEN, Conn., March 8, 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, today announced that on March 7, 2023, the United States Patent and Trademark Office ("USPTO") issued a notice of allowance for nalbuphine ER's method of treatment of chronic cough in IPF.

Trevi expects the resulting patent will be Orange Book-listable with an anticipated expiration in 2039. Trevi intends to continue to prosecute additional patent applications to further enhance its existing patent estate protecting nalbuphine ER across multiple chronic cough conditions as additional clinical data is generated.

"We are pleased with this allowance of claims to further secure IP protection for Haduvio through 2039 for the treatment of chronic cough in IPF," said Jennifer Good, President and CEO of Trevi Therapeutics. "We expect that this allowed patent application when issued will provide important protection along with the already issued formulation patents and other patent applications that we are prosecuting."

About Chronic Cough in Idiopathic Pulmonary Fibrosis
IPF is a serious, end-of-life disease. Chronic cough is one of the most common symptoms of IPF and has a significant impact on quality of life in these patients. There are estimated to be 140,000 IPF patients in the US and more than 1 million patients ex-US, where up to 85% of these patients experience chronic cough. There are no approved therapies for the treatment of chronic cough in IPF and the cough often isn't affected by antitussive therapy. Patients with chronic cough in IPF can cough up to 1,500 times per day, leading to increased feelings of fear and stress as it causes shortness of breath. Coughing spells or episodes lead to significant fatigue, an urge to breathe, low levels of oxygen in blood, and some patients also experience loss of bladder control. The social impact of chronic cough in IPF is increased because of limited exercise ability, reduced walking distance, and the need to use additional oxygen. Chronic cough in IPF may be an early clinical marker of disease activity that could potentially help to identify patients at high risk of progression and predict time to death or lung transplant. In addition, chronic cough in IPF may also contribute to enhanced activation of profibrotic mechanisms and disease worsening.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing Haduvio, an investigational therapy in an oral extended-release formulation of nalbuphine, for the treatment of chronic cough in IPF and other chronic cough indications. Haduvio is a mixed κ-opioid receptor agonist and μ-opioid receptor antagonist that works both centrally and peripherally. The μ and κ receptors are known critical mediators of cough. Parenteral nalbuphine has been approved and marketed for over 20 years for the treatment of acute pain indications and is not scheduled 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.

For more information, visit www.TreviTherapeutics.com and follow Trevi on 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 statements regarding the Company's intellectual property portfolio, 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; whether the patents and patent applications owned or licensed by the Company, such as the patent referred to in this release, will protect the Company's technology and prevent others from infringing it, 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 Trevi's Haduvio in the United States and foreign countries, including the Company's ability to submit and get clearance on an IND 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; 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.

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