

Trevi Therapeutics Announces License Agreements for use of Nalbuphine for the Treatment of Levodopa-Induced Dyskinesia (LID) in Parkinson's Disease

Agreements with Rutgers and MentiNova for exclusive worldwide rights to issued U.S. patents and pending patent applications

Trevi plans Phase 2 trial of nalbuphine ER for LID in patients with Parkinson's disease in 2019

New Haven, CT, February 4, 2019 – [Trevi Therapeutics, Inc.](#) (“Trevi”), a clinical-stage biopharmaceutical company focused on the development and commercialization of [nalbuphine ER](#) to treat serious neurologically mediated conditions, today announced that it had entered into exclusive license agreements with Rutgers, The State University of New Jersey and MentiNova, Inc. for intellectual property and data supporting the development of nalbuphine ER for levodopa-induced dyskinesia (LID) in patients with Parkinson's disease.

MentiNova was co-founded by Dr. M. Maral Mouradian, a movement disorders specialist and Endowed Chair for Parkinson's Research at Rutgers University. In preclinical research in a non-human primate model of Parkinson's disease, treatment with nalbuphine resulted in a statistically significant reduction in dyskinesia, maintaining anti-LID activity with chronic administration, and was safe and well tolerated.

“We believe that several serious neurologically mediated conditions share a common pathophysiology that is mediated through opioid receptors in the central and peripheral nervous system. We have been developing nalbuphine ER for chronic pruritic conditions and believe it also has the potential to be effective in LID, as supported by MentiNova's preclinical data. We look forward to advancing nalbuphine ER into a Phase 2 trial in Parkinson's patients with LID in 2019,” said Jennifer L. Good, Trevi's President & CEO.

Dr. Mouradian, President of MentiNova, said “I am pleased to see our preclinical work advance with Trevi as they move this program directly into patients with Parkinson's disease. We have studied the mechanism of action of nalbuphine and believe it has the potential to provide a much-needed therapeutic option for patients suffering from levodopa-induced dyskinesia.”

Under the terms of the agreements, Trevi has an exclusive license to two issued U.S. patents, one issued Japanese patent, and additional pending applications in the U.S., Canada and Europe, as well as associated know-how. These patents relate to the use of nalbuphine in various movement disorders, including LID.

About Levodopa-Induced Dyskinesia in Parkinson's Disease

In the United States, there are close to one million people living with Parkinson's disease, a chronic neurodegenerative disorder that primarily affects motor function, with an estimated 150,000 people having levodopa-induced dyskinesia. Levodopa, which replaces depleted dopamine in this condition, is considered the “gold standard” and the most effective therapy for Parkinson's disease. Over time, however, people with Parkinson's disease require increasingly higher or more frequent doses of levodopa to avoid recurrent periods when levodopa is ineffective. These periods are characterized by the return of the underlying symptoms of Parkinson's disease including slowness of movement, rigidity, impaired walking, tremors, and postural instability. Long-term treatment of Parkinson's disease with levodopa also frequently results in dyskinesia, which is characterized by involuntary movements that are non-rhythmic, purposeless and unpredictable, impacting peoples' daily lives. Approximately 62% of the estimated one million Parkinson's disease patients in the United States are treated with levodopa, and as the disease advances, approximately 50% of patients on levodopa therapy experience debilitating dyskinesia after 5 years and 90% do so after 15 years of levodopa therapy.

About Nalbuphine ER

Nalbuphine ER 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 or Europe.

About Rutgers, The State University of New Jersey

Rutgers, The State University of New Jersey, is a leading national research university and the state of New Jersey's preeminent, comprehensive public institution of higher education. Established in 1766, the university is the eighth oldest higher education institution in the United States. More than 70,000 students and 23,400 full- and part-time faculty and staff learn, work, and serve the public at Rutgers locations across New Jersey and around the world.

About Trevi Therapeutics, Inc.

Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of nalbuphine ER to treat serious neurologically mediated conditions. Trevi is currently developing nalbuphine ER 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 pivotal Phase 2b/3 clinical trial of nalbuphine ER, 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. For additional information, visit www.trevitherapeutics.com.

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