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Trevi Therapeutics Announces Initiation of a Pivotal Study of Nalbuphine ER in Uremic Pruritus

Study will enroll 360 patients in the United States and Europe

New Haven, CT, July 14, 2014 - Trevi Therapeutics, Inc. ("Trevi" or the "Company"), a clinical stage biotechnology company developing Nalbuphine ER for chronic pruritus conditions, today announced the first patient enrolled in the pivotal study of Nalbuphine ER in hemodialysis patients with uremic pruritus. The Company recently released data from its successfully completed Phase 1 trial in which Nalbuphine ER was well tolerated in hemodialysis patients and established proof-of-concept for Nalbuphine ER in treating uremic pruritus.

Jennifer L. Good, Trevi's President and Chief Executive Officer, said, "Approximately 40% of hemodialysis patients have moderate to severe pruritus that significantly impacts their quality of life. There are no approved therapies for this condition. The initiation of this pivotal study of Nalbuphine ER is a significant step forward in the development of a potential therapeutic treatment option for these patients."

Thomas R. Sciascia, M.D., Trevi's Chief Medical Officer, said, "There has been a significant amount of research done over a number of years hypothesizing that the mu antagonist/kappa agonist mechanism could be a good treatment option for patients suffering from chronic pruritus. This study is an important step in advancing the research that has been done around the world in chronic pruritus."

The multi-center, randomized, double-blind, placebo-controlled, parallel, three-arm study will evaluate the safety and anti-pruritic efficacy of Nalbuphine ER tablets in approximately 360 hemodialysis patients. The study will be conducted in the United States and Europe. The primary endpoint for the study will measure the change from worst itch at baseline in patients with moderate to severe uremic pruritus, treated with two doses of Nalbuphine ER. The study also includes other secondary endpoints, including patient perception of the burden of itch, quality of life effects of pruritus, and impact on sleep, anxiety and depression.

The study will consist of a titration period of two weeks, followed by a six week blinded period on a fixed dose of drug or placebo and a wash-out period. At the end of the wash-out period, patients may be eligible to roll over into a six month open label extension study. The Company expects topline data from this study in the fourth quarter of 2015.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical stage biotechnology company focused on developing Nalbuphine ER for chronic pruritus (itch). Pruritus develops in various dermatologic, metabolic, hematologic and neuropathic conditions. The Company is pursuing two conditions for clinical development: uremic pruritus and prurigo nodularis. Uremic pruritus is a persistent and debilitating itch in patients on dialysis that has been associated with increased mortality. Prurigo nodularis is a chronic dermatologic condition characterized by severely pruritic nodules on the skin that are independent of underlying etiology. There are no approved therapies in the US or EU for either condition.

Nalbuphine ER is an oral extended release opioid with a unique opioid receptor dual agonist/antagonist mechanism of action, which has shown efficacy in addressing pruritus in both animal studies and human clinical trials. Because of Nalbuphine ER's dual mechanism of action, the company believes it can have broad utility in treating chronic pruritus.

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

For additional information, visit www.trevitherapeutics.com.

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