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Trevi Therapeutics Announces Initiation of a Pivotal Study of Nalbuphine ER in Prurigo Nodularis

Study will enroll 60 patients in the United States and Europe

New Haven, CT, March 11, 2015 - [Trevi Therapeutics, Inc.](#) (“Trevi” or the “Company”), a late stage clinical development company developing [Nalbuphine ER](#) for chronic pruritus conditions, today announced the initiation of the Company’s pivotal study of Nalbuphine ER in patients with [prurigo nodularis](#), a severely pruritic dermatological condition characterized by itchy skin nodules. The Company is also currently conducting a pivotal trial with Nalbuphine ER in hemodialysis patients with [uremic pruritus](#), which is almost fully enrolled.

Jennifer L. Good, Trevi’s President and Chief Executive Officer, said, “Prurigo nodularis is an intensely pruritic disease that seriously impacts a patient’s quality of life. There are no approved therapies for this condition. The initiation of this 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, “The hypothesis of our study is that within an eight-week period there will be a significant reduction in itch. We are also offering a one-year open label extension to understand if a prolonged reduction in itching will result in the healing of the skin.”

The multi-center, randomized, double-blind, placebo-controlled, parallel, three-arm study will evaluate the safety and anti-pruritic efficacy of Nalbuphine HCl ER tablets in approximately 60 prurigo nodularis patients. The study will be conducted in the United States and Europe. The primary endpoint for the study will measure the change in itch from baseline in prurigo nodularis patients with moderate to severe itch. 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 an eight-week blinded period on a fixed dose of drug or placebo and a two-week wash-out period. At the end of the wash-out period, patients may be eligible to roll over into a one-year open label extension study. For more information on the Study of Nalbuphine HCl ER Tablets in Patients With Prurigo Nodularis, visit [ClinicalTrials.gov](#). The Company expects topline data from this study in the third quarter of 2015.

About Trevi Therapeutics, Inc.

Trevi Therapeutics, Inc. is a late-stage clinical development 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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