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Trevi Therapeutics Announces Completion of Enrollment in Phase 2/3 Study of Nalbuphine ER in Prurigo Nodularis

Company expects to report data in Q3 2016

New Haven, CT, June 2, 2016 - Trevi Therapeutics, Inc. ("Trevi" or the "Company"), a late stage clinical development company developing Nalbuphine ER for chronic pruritus conditions, today announced the completion of enrollment in a pivotal study of Nalbuphine ER in patients with prurigo nodularis. Prurigo nodularis (PN) is a severely pruritic dermatological condition characterized by itchy skin papules and nodules, and has no approved therapies. In its most recent data release in Q4 2015, Trevi reported positive results from another pivotal trial with Nalbuphine ER in hemodialysis patients with uremic 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 63 prurigo nodularis patients in the US and Europe. The primary endpoint for the study is a reduction in itch intensity as measured by the Numerical Rating Scale in patients with moderate to severe pruritus from PN. The study also includes several other secondary endpoints, including patient perception of the burden of itch, quality of life effects of pruritus, and impact on sleep and mood.

The study consists of a titration period of two weeks, followed by an eight-week blinded period on a fixed dose of the drug or placebo and a wash-out period. At the end of the wash-out period, patients are eligible to roll-over into a one-year open label extension study which will help generate data on the safety and duration of the effects of the drug and whether prolonged reduction in itching results in the healing of the skin lesions characteristic of prurigo nodularis.

Jennifer L. Good, Trevi's President and Chief Executive Officer, said, "We are very pleased about the completion of the enrollment for this trial in a population with great unmet need. We look forward to reporting the final data in the third quarter of 2016 and being able to bring this first ever treatment forward for patients."

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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