



Trevi Therapeutics Announces Completion of Enrollment in Pivotal Study of Nalbuphine ER in Uremic Pruritus

March 31, 2015

Study enrolls four months ahead of schedule

New Haven, CT, March 31, 2015 – [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 the pivotal study of Nalbuphine ER in hemodialysis patients with [uremic pruritus](#). The Company commenced this trial in June 2014.

Jennifer L. Good, Trevi’s President and Chief Executive Officer, said, “We are very pleased that this trial has enrolled significantly ahead of schedule. We believe it speaks to the seriousness of moderate to severe uremic pruritus for patients on hemodialysis and the lack of good treatment options. We look forward to seeing the data and determining the next steps in being able to bring this treatment to patients.”

Thomas R. Sciascia, M.D., Trevi’s Chief Medical Officer, said, “The rate of enrollment in this trial confirms that there are a significant number of these patients with moderate to severe uremic pruritus, despite on-going hemodialysis. In addition, we have seen a strong rollover rate of these patients into our six month open label extension trial. We look forward to following their progress.”

The multi-center, randomized, double-blind, placebo-controlled, parallel, three-arm study evaluates the safety and anti-pruritic efficacy of Nalbuphine ER tablets dosed twice-daily in approximately 360 hemodialysis patients 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. Other secondary endpoints include patient perception of the burden of itch, quality of life effects of pruritus, and impact on sleep, anxiety and depression.

The study consists 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 are eligible to roll over into a six-month open label extension study. 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 dual mechanism of action, mu receptor antagonist and kappa receptor agonist, both of which have been shown in research to be effective in abolishing itch. Because of Nalbuphine ER’s unique dual mechanism of action, which has shown efficacy in addressing pruritus in both animal studies and human clinical trials, 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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