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Trevi Therapeutics Announces Positive Results from Phase 2 Trial in Prurigo Nodularis

Oral Nalbuphine®ER trial achieved positive results of reduced itch intensity and other supporting efficacy endpoints in prurigo nodularis patients

New Haven, CT, October 13, 2016 – Trevi Therapeutics, Inc. ("Trevi" or the "Company"), a late-stage clinical development company developing oral Nalbuphine®ER for chronic pruritus conditions, today announced positive results from its Phase 2 trial for the treatment of moderate to severe prurigo nodularis. Prurigo nodularis (PN), a severely pruritic dermatological condition characterized by itchy skin papules and nodules, has significant impact on quality of life and has no approved therapies. Trevi also previously reported statistically significant results from a robust Phase 2/3 trial with Nalbuphine ER in hemodialysis patients with uremic pruritus.

The multi-center, randomized, double-blind, placebo-controlled, parallel, three-arm study evaluated the safety and anti-pruritic efficacy of Nalbuphine ER tablets dosed twice-daily at 90mg and 180mg in 62 patients in the United States and Europe. Patients with moderate-to-severe itch intensity, defined as ≥ 5 on the 0-10 Numerical Rating Score (NRS) scale, were enrolled to evaluate drug efficacy across a representative patient population for treatment of this chronic indication. The actual average baseline worst itch for enrolled patients was ≥ 8, indicating the severe nature of the disease.

The study consisted 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 were eligible to roll over into a one-year open label extension study. The Company expects the open label extension study to be completed in the third quarter of 2017.

The main outcome variables for this study were responder analyses of the proportion of patients with at least a 30% or 50% reduction in their 7-day worst-itch intensity NRS from baseline to completion of treatment at week 10 or last observation visit. The proportion of patients in the Nalbuphine ER 180 mg BID arm meeting 50% responder criteria at week 10 or last observed visit (MITT population with n=18)

approached statistical significance (p=0.083), and this arm met statistical significance for patients (n=12) completing treatment (p=0.028). The mean change in worst itch NRS was additionally evaluated, and the MITT population of the Nalbuphine ER 180 mg BID arm as compared to placebo approached statistical significance (p=0.083) as well. This arm also met statistical significance for patients (n=12) completing treatment (p=0.025).

The ItchyQoL™ secondary endpoint, 22 questions that measure how pruritus affects a patient's quality of life, provided supportive evidence of a favorable treatment effect on reduction in itch intensity compared to placebo. Change from baseline in the ItchyQoL total score was significantly more favorable for the Nalbuphine ER 180 mg BID dose compared to placebo (p=0.022).

The most common adverse events in the study were dizziness, nausea, headaches, and fatigue, the majority of which were grade 1 or 2. As seen previously, the incidence rate of these events was similar to placebo after the titration period. No serious adverse events attributed to the drug were observed, and the study DSMB raised no issues that affected the continuation of the study or required modification of study procedures.

Jennifer L. Good, Trevi's President and Chief Executive Officer, said, "We have now demonstrated that Nalbuphine ER can improve pruritus in two very different and severe itch conditions: prurigo nodularis and uremic pruritus. Itch is a significant unmet medical need resulting from many diseases in dermatology, oncology, hepatology and neurology, and we believe Nalbuphine ER may provide an important therapy for these patients."

Thomas R. Sciascia, M.D., Trevi's Chief Medical Officer, said, "Prurigo nodularis is a very serious dermatologic condition, with no approved therapies. Once a patient gets PN, they may cope with the disease for many years, with significant impact on their ongoing quality of life. We are pleased with the results of our trial, and are preparing for a discussion with both FDA and EMA about the development path forward with the critical mass of data we have gathered."

Trevi is preparing for an end of Phase 2 meeting for prurigo nodularis, has already held an end of Phase 2 meeting with FDA for uremic pruritus, and will initiate Phase 3 trials in both conditions in 2017.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a late-stage clinical development company developing oral Nalbuphine®ER for chronic pruritus conditions (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 skin nodules that are

independent of underlying etiology. There are no approved therapies in the United States or Europe for either condition.

Nalbuphine ER is an oral extended release mu receptor antagonist and kappa receptor agonist. Both modalities have been shown to be effective in abolishing itch. Trevi believes that Nalbuphine ER's unique dual mechanism of action, which has shown efficacy in addressing pruritus in both animal studies and human clinical trials, may 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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