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Trevi Therapeutics Initiates Pivotal Clinical Trial of Nalbuphine® ER for the Treatment of Pruritus in Prurigo Nodularis

Pruritus Relief thru Itch-Scratch Modulation ("PRISM") Trial to enroll 240 patients and evaluate efficacy of Nalbuphine ER at 14 weeks

New Haven, CT, September 27, 2018 – Trevi Therapeutics, Inc. ("Trevi"), a late-stage biopharmaceutical company focused on developing Nalbuphine® ER for chronic pruritic and other serious neurological conditions, today announced initiation of a pivotal clinical trial evaluating Nalbuphine ER in patients with pruritus in prurigo nodularis (PN). PN is a severely pruritic dermatological condition characterized by nodules and papules with excoriations and ulcerations for which there are no approved therapies. The PRISM trial is a randomized, double-blind, placebo-controlled, two-arm study, with an open label extension period following double blind treatment. The study will enroll 240 eligible patients that will be randomized 1:1 to receive either oral Nalbuphine ER 162 mg twice daily or placebo.

"PRISM represents the most robust clinical trial conducted in PN to date, with 240 patients being studied over 14 weeks, and the opportunity for patients to continue into a one year open-label extension study. We believe studying the long-term safety as well as the nodule and excoriation healing of the skin is very important in this disease and in establishing the value of Nalbuphine ER," said Jennifer L. Good, President and Chief Executive Officer.

"We are excited to initiate this robust pivotal trial following the positive results achieved in our Phase 2 trial of Nalbuphine ER which reduced itch intensity in PN, together with improving other supportive efficacy endpoints in PN. We are now enrolling patients in the US and plan to open sites in Europe by the end of 2018," said Dr. Helena Brett-Smith, Chief Development Officer.

PRISM Pivotal Trial Design

The PRISM trial is a randomized, double-blind, placebo-controlled, parallel, two-arm 14 week treatment study that will evaluate the safety and anti-pruritic efficacy of Nalbuphine ER 162 mg tablets in 240 PN patients with severe pruritus from PN in approximately 40 centers in the US and Europe.

The primary efficacy endpoint for the study is the proportion of patients achieving at least a 4-point improvement from baseline with respect to their worst itch at week 14 as measured by the Numerical Rating Scale. The study also includes several other secondary endpoints, including quality of life measurements and skin healing.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a late-stage biopharmaceutical company focused on developing Nalbuphine ER for chronic pruritic and other serious neurological conditions. Pruritus develops in various dermatologic, metabolic, hematologic and neuropathic conditions. The Company is pursuing several pruritic conditions for clinical development, including its lead indication of prurigo nodularis. Prurigo nodularis is a chronic pruritic dermatologic condition characterized by the presence of pruriginous lesions on the skin and major alteration on the quality of life of the patients. There are no approved therapies in the U.S. or EU for this condition.

Nalbuphine ER is a unique oral extended release mixed mu receptor antagonist and kappa receptor agonist, both of which have been shown in research to be effective in abolishing itch, and which the neurobiology indicates has a dynamic and synergistic relationship. Because of Nalbuphine ER's unique dual mechanism of action, which has shown efficacy in two difficult to treat pruritus conditions of prurigo nodularis and uremic pruritus, the Company believes Nalbuphine ER can potentially have broad utility in treating chronic pruritus.

Founded in 2011, Trevi Therapeutics is headquartered in New Haven, CT. For additional information, visit www.trevitherapeutics.com.

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Media contact:
Laura Brophy
(203) 331-7618
lbrophy@marketcompr.com