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Trevi Therapeutics Presents Data at the 7th World Congress on Itch

Nalbuphine attenuates itch in the substance P induced mouse model

New Haven, CT, September 25, 2013 – [Trevi Therapeutics, Inc.](#) (“Trevi”), a clinical stage biotechnology company focused on developing [Nalbuphine ER](#) for chronic pruritus, presented data on nalbuphine at the [7th World Congress on Itch](#).

Nalbuphine is a mixed mu antagonist/kappa agonist opioid. The effect of nalbuphine on substance P induced scratching was studied by Trevi in the mouse model. This model is relevant to antihistamine-resistant pruritus, which is observed in patients with various dermatopathologies. Following substance P administration in the untreated mice, itching began within 3-5 minutes from the pruritogen administration with the highest itch intensity in the first 30 minutes post substance P injection. Following nalbuphine administration, a significant reduction in itch ($p < 0.001$) was noted with a 43% reduction in itch at the 10 mg/kg dose and a 51% reduction at the 30 mg/kg dose.

The published literature on nalbuphine suggests a centrally mediated effect. The substance P mouse model conducted by Trevi suggests nalbuphine can be effective as well in the treatment of peripherally mediated pruritic conditions. This evidence of a centrally and peripherally mediated effect potentially makes Nalbuphine ER a good therapy for various chronic pruritic conditions.

Thomas Sciascia, MD, Trevi’s co-founder and Chief Medical Officer, said, “We are currently completing a Phase 1 trial in renally impaired patients to establish safety in this patient population, and are preparing to initiate an efficacy study in uremic pruritus in

the first half of 2014. In parallel, we plan to initiate a Phase 2 study in a serious dermatologic condition, prurigo nodularis, in the same time period.”

About Trevi Therapeutics, Inc.

Trevi Therapeutics, Inc. is a clinical stage biotechnology 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 pruritic nodules on the skin that are independent of underlying etiology, but instead result as a clinical reaction pattern due to long-term trauma of the pruritic skin.

Nalbuphine ER is an oral extended release opioid with a unique opioid receptor dual agonist/antagonist mechanism of action, which has been shown in both animal studies and human clinical trials as being effective in pruritus. 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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