

Trevi Therapeutics Commences Clinical Study of Nalbuphine ER

Phase 1 Study in End-Stage Renal Disease Patients on Hemodialysis

New Haven, CT, May 6, 2013 – [Trevi Therapeutics, Inc.](#) (“Trevi”), a drug development company focused on developing [Nalbuphine ER](#) for chronic pruritus, announced today that it has commenced a Phase 1, open-label study to characterize and compare the pharmacokinetics, safety and tolerability of escalating oral doses of nalbuphine hydrochloride extended release tablets in end-stage renal disease patients on hemodialysis as compared to healthy control subjects. The study will include 20 subjects and top-line data is expected by year-end.

Nalbuphine ER is an oral extended release formulation of nalbuphine hydrochloride which has previously only been approved as an injectable. Nalbuphine has a unique opioid receptor dual agonist/antagonist mechanism of action and has been shown in both animal and human clinical studies as being effective in pruritus. Because of the drug’s centrally acting dual mechanism of action, the Company believes Nalbuphine ER may have broad utility in treating chronic pruritus.

Jennifer Good, Trevi’s Co-founder and President and CEO, said, “We have strong momentum inside [Trevi](#) as we initiate this important trial to establish the safety of Nalbuphine ER in the intended patient population of renally impaired patients and prepare to initiate an efficacy study in uremic pruritus in early 2014. We are also actively pursuing a second indication in dermatology and anticipate initiating that efficacy trial next year as well.”

About Trevi Therapeutics, Inc.

Trevi Therapeutics, Inc. is a drug 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 uremic pruritus as the lead indication. Uremic pruritus is a persistent and debilitating itch in patients on dialysis that has been associated with increased mortality. 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 and human clinical studies as being effective in pruritus. Because of Nalbuphine ER’s centrally acting dual mechanism of action, the company believes it can have broad utility in treating chronic pruritus and is actively pursuing a second indication in dermatology. Founded in 2011, Trevi is headquartered in New Haven, CT.

For additional information, visit www.trevitherapeutics.com.

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