Trevi Therapeutics Announces Third Quarter 2019 Financial Results and Recent Business Developments

November 14, 2019

Advancement of Nalbuphine ER in Clinical Development for Three Indications

Cash Position of $63.5 Million Expected to Fund Operations Through At Least Q1 2021

NEW HAVEN, Conn., Nov. 14, 2019 (GLOBE NEWSWIRE) -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company focused on the development and commercialization of nalbuphine ER to treat serious neurologically mediated conditions, today announced financial results for the quarter ended September 30, 2019, as well as recent business highlights.

"We have made substantial progress this year advancing the development of nalbuphine ER across all of our clinical indications. We continued to progress our lead development program in prurigo nodularis during the third quarter with further enrollment and continued site initiations in Europe and the US. We have had 100% of the patients that completed the blinded 14-week dosing continue into the open label extension portion of the study," said Jennifer L. Good, President and CEO of Trevi Therapeutics. "We are also actively enrolling the cough study in idiopathic pulmonary fibrosis patients in the UK and have completed dosing of subjects with mild to moderate liver impairment in our Phase 1b study in patients with chronic liver disease. While the pace of enrollment in our PN trial has been slower than originally planned, our team remains focused on completing this trial, as well as those in our other clinical indications, each of which represents a significant unmet medical need."

Product Pipeline Updates

- Phase 2b/3 PRISM trial: The ongoing PRISM trial is a randomized, double-blind, placebo controlled, two-arm treatment study that is designed to evaluate the safety and anti-pruritic efficacy of nalbuphine ER in approximately 240 patients with severe pruritus from PN in approximately 50 centers in the U.S. and Europe. To date, the Company has enrolled approximately 30% of the targeted number of patients in the study. The pace of enrollment has been slower than anticipated primarily due to competition from other clinical trials and slower than planned site start-ups in Europe. As a result, the Company expects to report top-line data from the PRISM trial in the second half of 2020. Additionally, the protocol for the PRISM trial provides for a sample size re-estimation analysis once 50% of the patients in the trial are evaluable for the primary endpoint. Trevi expects the re-estimation analysis will occur in mid-2020.
- Phase 2 trial of nalbuphine ER for chronic cough in patients with idiopathic pulmonary fibrosis (IPF): The Phase 2 clinical trial is a randomized, double-blind, placebo controlled, two-treatment, two-period, crossover study designed to evaluate the efficacy, safety, tolerability and dosing of nalbuphine ER for chronic cough in up to 56 patients with IPF. Patient enrollment is underway and Trevi expects to activate all remaining clinical sites by the end of 2019. Trevi expects to complete enrollment in this trial in the first half of 2020 and report top-line data in the second half of 2020.
- Phase 1b trial in patients with chronic liver disease: Trevi completed the Phase 1b single ascending dose segment of the hepatic impairment study in subjects with mild and moderate liver impairment. There were no serious adverse events reported and based on the safety and PK profile observed in the study, planning is underway for a Phase 2 trial of nalbuphine ER in patients with pruritus associated with primary biliary cholangitis (PBC). In addition, Trevi intends to use data from the hepatic impairment study to support a submission of a New Drug Application (NDA) for nalbuphine ER for pruritus in PN.
- Phase 2 trial of levodopa-induced dyskinesia (LID) in patients with Parkinson's disease: Trevi has written the protocol for a Phase 2 trial for LID in patients with Parkinson's disease and plans to submit an Investigational New Drug Application (IND) to the U.S. Food and Drug Administration (FDA) in the upcoming months.

Third Quarter 2019 Financial Highlights

Cash position: As of September 30, 2019, Trevi reported total cash and cash equivalents of $63.5 million compared to $7.2 million as of December 31, 2018. Trevi believes this cash position will be sufficient to fund operations through at least the end of the first quarter of 2021.

Research and development (R&D) expenses: R&D expenses for the third quarter of 2019 were $5.6 million compared to $3.7 million in the same period in 2018. The increase was primarily due to increased activities in several clinical trials including the Phase 2b/3 PRISM trial, the Phase 2 trial in chronic cough in patients with IPF and the Phase 1b trial in patients with chronic liver disease.

General and administrative (G&A) expenses: G&A expenses for the third quarter of 2019 were $2.0 million compared to $1.2 million in the same period in 2018. The increase was primarily due to an increase in personnel and stock-based compensation expense as well as expenses related to being a public company.

Net loss: For the third quarter of 2019, Trevi reported a net loss of $7.4 million compared to a net loss of $5.7 million in the same

period in 2018.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of nalbuphine ER to treat serious neurologically mediated conditions. Trevi is currently developing nalbuphine ER for the treatment of chronic pruritus, chronic cough in patients with idiopathic pulmonary fibrosis (IPF) and levodopa-induced dyskinesia (LID) in patients with Parkinson's disease. These conditions share a common pathophysiology that is mediated through opioid receptors in the central and peripheral nervous systems. Trevi is currently conducting a Phase 2b/3 clinical trial of nalbuphine ER, referred to as the PRISM trial, in patients with severe pruritus associated with prurigo nodularis (PN).

Founded in 2011, Trevi Therapeutics is headquartered in New Haven, CT.

About Nalbuphine ER
Nalbuphine ER is an oral extended release formulation of nalbuphine. Nalbuphine is a mixed κ-opioid receptor agonist and μ-opioid receptor antagonist that has been approved and marketed as an injectable for pain indications for more than 20 years in the United States and Europe. The κ- and μ-opioid receptors are known to be critical mediators of itch, cough and certain movement disorders. Nalbuphine's mechanism of action also mitigates the risk of abuse associated with μ-opioid agonists because it antagonizes, or blocks, μ-opioid receptors. Nalbuphine is currently the only opioid approved for marketing that is not classified as a controlled substance in the United States and most of Europe.

Forward-Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the expected timing of the re-estimation analysis for, and for reporting top-line data from, Trevi's Phase 2b/3 PRISM trial of nalbuphine ER in patients with prurigo nodularis; the expected timing of milestones for the Company's other ongoing and planned clinical trials; Trevi's business plans and objectives, including future plans or expectations for Trevi's product candidates and expectations regarding Trevi's uses and sufficiency of capital; and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties regarding the success, cost, and timing of the Trevi's product candidate development activities and planned clinical trials; uncertainties regarding Trevi's ability to execute on its strategy; the risk that positive results from a clinical trial may not necessarily be predictive of the results of future or ongoing clinical trials; potential regulatory developments in the United States and foreign countries; uncertainties inherent in estimating future expenses, capital requirements and other financial results; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended June 30, 2019 filed with the Securities and Exchange Commission and in subsequent filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Trevi undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Trevi Therapeutics, Inc.
Selected Balance Sheet Data
(unaudited)
(amounts in thousands)

Cash and cash equivalents
Working capital
Total assets
Stockholders' equity (deficit)

Trevi Therapeutics, Inc.
Selected Statement of Operations Data
(unaudited)
(amounts in thousands)

	Three Months Ended

	September 30, 2019	
Operating expenses:		
Research and development	$ 5,650	$
General and administrative	2,000	
Total operating expenses	7,650	
Loss from operations	(7,650)	
Other income (expense), net	280	
Loss before income tax benefit	(7,370)	
Income tax benefit	5	
Net loss	$ (7,365)	$

Investor Contact
Peter Vozzo
Westwicke
peter.vozzo@westwicke.com
443-213-0505

Media Contact
Rosalia Scampoli
rscampoli@marketcompr.com
212-537-5177 ext. 7