TREVI THERAPEUTICS ANNOUNCES FOURTH QUARTER AND YEAR END 2019 FINANCIAL RESULTS AND CORPORATE UPDATE

March 16, 2020

Enrollment in PRISM Study Progressing - Sample Size Re-estimation Planned for mid-2020

Expect to Report Top-Line Data in both PN and IPF-Cough Trials in Second Half of 2020

Cash Position of $57.3 Million Expected to Fund Operations into the Third Quarter of 2021

NEW HAVEN, Conn., March 16, 2020 (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 and year ended December 31, 2019, as well as recent business highlights.

"We made substantial progress in 2019 advancing the development of nalbuphine ER across our clinical indications and expect 2020 to be an important year for Trevi with clinical data expected in our two lead indications. We continued to progress our lead development program in prurigo nodularis, and expect to achieve 50% enrollment in the PRISM study in the second quarter of 2020 with the sample size re-estimation in mid-2020 and top-line data from this study in the second half of 2020," 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 expect to report top-line data in the second half of 2020 as well."

Key Product Pipeline Updates

- Phase 2b/3 PRISM trial of nalbuphine ER for severe pruritus in patients with prurigo nodularis (PN): 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 60 centers in the U.S. and Europe. To date, the Company has enrolled approximately 45% of the targeted number of patients in the study. 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 to reach 50% patient enrollment during the second quarter of 2020 and that 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 ongoing 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 report top-line data in the second half of 2020.

Fourth Quarter 2019 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the fourth quarter of 2019 were $4.8 million compared to $4.5 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 and the Phase 2 trial in chronic cough in patients with IPF.

General and administrative (G&A) expenses: G&A expenses for the fourth quarter of 2019 were $1.9 million compared to $1.4 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 fourth quarter of 2019, Trevi reported a net loss of $6.5 million compared to a net loss of $6.0 million in the same period in 2018.

Year End 2019 Financial Highlights

Cash position: As of December 31, 2019, total cash and cash equivalents were $57.3 million compared to $7.2 million as of December 31, 2018. Trevi believes this cash position will be sufficient to fund operations into the third quarter of 2021.

R&D expenses: R&D expenses for the year ended December 31, 2019 were $19.3 million compared to $14.1 million for the year ended December 31, 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.

G&A expenses: G&A expenses for the year ended December 31, 2019 were $7.3 million compared to $4.3 million for the year ended December 31, 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 year ended December 31, 2019, Trevi reported a net loss of $26.1 million compared to a net loss of $20.5 million for the year ended December 31, 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 enrollment and 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 ongoing 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 September 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 December 31,	
	2019	2018
Operating expenses:		
Research and development	$ 4,823	$ 4,523
General and administrative	1,943	1,406
Total operating expenses	6,766	5,929
Loss from operations	(6,766)	(5,929)
Other income (expense), net	225	(102)
Loss before income tax benefit	(6,541)	(6,031)
Income tax benefit	4	49
Net loss	$ (6,537)	$ (5,982)

Investor Contact
Chris Seiter, Chief Financial Officer
Trevi Therapeutics, Inc.
chris.seiter@trevitherapeutics.com
203-304-2499

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