Trevi Therapeutics Announces First Quarter 2020 Financial Results and Corporate Update

Sample Size Re-Estimation Analysis for PRISM Trial Expected in Mid-2020

New Patient Screening Re-Starting at PRISM Sites in the US and Europe

Cash Position of $52.6 Million Expected to Fund Operations into the Fourth Quarter of 2021

NEW HAVEN, Conn., May 07, 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 ended March 31, 2020, as well as recent business highlights.

“We are pleased to announce that we have completed enrollment of the patients necessary to conduct the sample size re-estimation analysis in our PRISM trial and expect to announce the results of this analysis in mid-2020,” said Jennifer L. Good, President and CEO of Trevi Therapeutics. “With the ongoing COVID-19 pandemic, we have experienced some disruption to new patient screening and enrollment in the PRISM trial, however, our clinical sites are beginning to screen new patients and we expect most of our sites will begin to screen and enroll new patients in May and June. Importantly, we have not had any patient discontinuations in the blinded portion of the trial related to COVID-19 and substantially all patients on treatment were able to complete their required visits. We plan to provide guidance on the expected timing of top-line results from the PRISM trial when we announce the results from the sample size re-estimation analysis in mid-2020.”

Key Product Pipeline Updates

- Phase 2b/3 PRISM trial of nalbuphine ER for severe pruritus in patients with prurigo nodularis: The pace of enrollment in the PRISM trial has been impacted by the COVID-19 pandemic with new patient screening and most patient enrollment temporarily halted. Patient screening restrictions have been lifted in the United States and are in the process of being lifted in Europe. We expect many of our sites will restart patient screening and enrollment throughout May and June 2020. The protocol for the PRISM trial provides for a sample size re-estimation (SSRE) analysis once approximately 50% of the patients in the trial are evaluable for the primary endpoint. In light of the pandemic-related delays, we have decided to conduct the SSRE analysis once approximately 45% of the patients in the trial are evaluable for the primary endpoint. We have enrolled all the patients that will be included in the SSRE and will conduct the SSRE analysis once the last of these patients has completed the 14-week blinded treatment period. We expect the SSRE analysis will occur in mid-2020. We plan to provide guidance on our expected timing to report top-line data from the 14-week blinded treatment period of the PRISM trial when we report the results of the SSRE analysis in mid-2020 based on the results of the SSRE analysis and our progress in restarting patient screening and enrollment related to COVID-19.
- Phase 2 trial of nalbuphine ER for chronic cough in patients with idiopathic pulmonary fibrosis (IPF): Due to the COVID-19 pandemic, and the specific at-risk nature of IPF patients, our clinical sites halted their enrollment and treatment of patients in this trial. We believe that enrollment may restart in the second half of 2020 and plan to provide guidance on the expected timing of top-line data from the trial in the second half of 2020.

First Quarter 2020 Financial Highlights

Cash position: As of March 31, 2020, Trevi reported total cash and cash equivalents of $52.6 million, compared to $57.3 million as of December 31, 2019. Trevi believes this cash position will be sufficient to fund operations into the fourth quarter of 2021.

Research and development (R&D) expenses: R&D expenses for the first quarter of 2020 were $6.0 million compared to $3.3 million in the same period in 2019. The increase was primarily due to increased activity in our Phase 2b/3 PRISM trial and our Phase 2 trial in chronic cough in patients with IPF as well as an increase in expenses related to the purchase of clinical trial supplies.

General and administrative (G&A) expenses: G&A expenses for the first quarter of 2020 were $2.6 million compared to $1.5 million in the same period in 2019. The increase was primarily due to an increase in stock-based compensation expenses and an increase in expenses related to being a public company.

Net loss: For the first quarter of 2020, Trevi reported a net loss of $8.5 million, compared to a net loss of $4.8 million in the same period in 2019.

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 and 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 impact of the COVID-19 pandemic on our clinical trials, business and operations, the expected timing of enrollment and the sample size 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 Trevi's product candidate development activities and ongoing and planned clinical trials; uncertainties regarding the scope, timing and severity of the COVID-19 pandemic and actions taken in response to the pandemic; 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 annual report on Form 10-K for the year ended December 31, 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)

	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 52,640	$ 57,313
Working capital	46,614	54,353
Total assets	54,238	60,001
Stockholders' equity	46,802	54,545

Trevi Therapeutics, Inc.

Selected Statement of Operations Data

(unaudited)

(amounts in thousands)

	Three Months Ended March 31,	
	2020	2019
Operating expenses:		
Research and development	$ 6,019	$ 3,338
General and administrative	2,620	1,474
Total operating expenses	8,639	4,812
Loss from operations	(8,639)	(4,812)
Other income (expense), net:	157	6
Loss before income tax benefit	(8,482)	(4,806)
Income tax benefit	9	4
Net loss	$ (8,473)	$ (4,802)

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