Trevi Therapeutics Announces First Quarter 2021 Financial Results and Business Update

Phase 2b/3 PRISM (Chronic Pruritus in PN) Trial Over 70% Enrolled
Phase 2 CANAL (Chronic Cough in IPF) Trial Resumes Screening at Multiple Sites
Fast Track Designation Granted by FDA for Moderate to Severe Pruritus in Prurigo Nodularis (PN)

NEW HAVEN, Conn., May 13, 2021 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company focused on the development and commercialization of the investigational therapy Haduvio™ (nalbuphine ER) to treat serious neurologically mediated conditions, today announced financial results for the quarter ended March 31, 2021, as well as business updates.

Fast Track Designation Granted by FDA for Moderate to Severe Pruritus in Prurigo Nodularis (PN)

"We continue to make progress in our clinical development programs for the treatment of chronic pruritus in patients with PN and chronic cough in patients with Idiopathic Pulmonary Fibrosis (IPF)," said Jennifer L. Good, President and CEO of Trevi Therapeutics. "Our PRISM trial is over 70% enrolled and we expect to complete enrollment in the second half of this year. We also recently received FDA Fast Track designation for moderate to severe pruritus in PN, evidencing the seriousness of this condition. In addition, our CANAL trial has resumed screening subjects since the COVID-19 shelter in place directive was lifted at the end of March in the UK and we are very pleased to see screening activity resume. We remain focused on completing enrollment in both trials and planning for the next steps in clinical development," concluded Ms. Good.

Key Business Updates

- **Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with mild to severe prurigo nodularis:** The PRISM trial has enrolled approximately 255 out of the planned 360 total subjects in the trial. We expect to complete enrollment in the second half of 2021, with top-line data to be reported approximately four months after enrollment is complete.

  The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to nalbuphine ER for the proposed indication of reduction of moderate to severe pruritus in patients with prurigo nodularis. Fast Track designation is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously.

- **Phase 2 CANAL trial of Haduvio for chronic cough in patients with idiopathic pulmonary fibrosis:** Sites for our CANAL trial have resumed screening since the UK's shelter in place order was lifted at the end of March 2021. We continue to work with the sites in the U.K. that have not yet resumed screening to fully reopen the trial.

First Quarter 2021 Financial Highlights

Cash position: As of March 31, 2021, the Company had total cash and cash equivalents of $41.6 million, compared to $45.0 million as of December 31, 2020. The Company expects its current cash position will fund operations into the second quarter of 2022.

Research and development (R&D) expenses: R&D expenses for the first quarter of 2021 were $5.6 million compared to $6.0 million in the same period in 2020. The decrease was primarily due to a decrease in clinical development expenses related to decreased purchases of clinical trial supplies and decreased expenses reflecting the completion of our Phase 1b clinical trial in patients with chronic liver disease in the first half of 2020. These decreased clinical development expenses were partially offset by increased costs associated with higher activity and enrollment in the Company's ongoing Phase 2b/3 PRISM trial, an increase in personnel-related expenses and higher consulting and professional fees.

General and administrative (G&A) expenses: G&A expenses for the first quarter of 2021 were $2.5 million compared to $2.6 million in the same period in 2020. The decrease was primarily due to a decrease in stock-based compensation expense.

Net loss: For the first quarter of 2021, the Company reported a net loss of $8.4 million, compared to a net loss of $8.5 million in the same period in 2020.

Conference Call

As previously announced, the Company will host a conference call and webcast today, Thursday, May 13, 2021 at 4:30 p.m. ET. To participate in the live conference call by phone, please dial (888) 317-6003 (domestic) or (412) 317-6061 (international) and provide access code 6116464. A live audio webcast will be accessible from the 'Investors & News' section on the Company's website at www.trevitherapeutics.com. An archived replay of the webcast will also be available for 30 days on the Company's website following the event.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of the investigational therapy Haduvio to treat serious neurologically mediated conditions. Trevi is conducting a Phase 2b/3 clinical trial of Haduvio for the treatment of chronic pruritus associated with prurigo nodularis (PN) and a Phase 2 trial for chronic cough in patients with idiopathic pulmonary fibrosis (IPF). Trevi is also developing Haduvio for the treatment of 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.

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

About Haduvio
Haduvio, an investigational therapy, 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 may also mitigate the risk of abuse associated with μ-opioid agonists because it antagonizes, or blocks, μ-opioid receptors. Nalbuphine is not currently classified as a controlled substance by the DEA in the United States and by regulatory authorities in most of Europe. Trevi intends to propose Haduvio as the trade name for nalbuphine ER. Haduvio is an investigational therapy that has been granted Fast Track designation by FDA for the proposed indication of reduction of moderate to severe pruritus in patients with prurigo nodularis. Its safety and efficacy have not been evaluated by any regulatory authority.

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 Trevi's clinical trials, business and operations; the expected timing of enrollment and for reporting top-line data from Trevi's Phase 2b/3 PRISM trial of Haduvio in patients with prurigo nodularis; Trevi's business plans and objectives, including future plans or expectations for Trevi's product candidates; 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, the impact of the COVID-19 pandemic on Trevi's clinical operations 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 regarding fast track designation and the effect such status could have on the regulatory review or approval process; uncertainties inherent in estimating Trevi's cash runway, future expenses 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, 2020 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, 2021	December 31, 2020
Cash and cash equivalents	$ 41,570	$ 45,001
Working capital	36,821	40,714

Total assets	42,864	47,131
Total debt	14,099	13,954
Stockholders' equity	23,685	27,282

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

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 5,589	$ 6,019
General and administrative	2,500	2,620
Total operating expenses	8,089	8,639
Loss from operations	(8,089)	(8,639)
Other (expense) income, net	(297)	157
Loss before income tax benefit	(8,386)	(8,482)
Income tax benefit	15	9
Net loss	$ (8,371)	$ (8,473)

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