Trevi Therapeutics Announces Fourth Quarter and Year End 2020 Financial Results and Business Updates

Expects to Complete Enrollment and Report Top-Line Data of the Phase 2b/3 PRISM Trial in Second Half of 2021

Cash Position Expected to Fund Operations into the Second Quarter of 2022

NEW HAVEN, Conn., March 25, 2021 (GLOBE NEWSWIRE) -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company focused on the development and commercialization of Haduvio™ (nalbuphine ER) to treat serious neurologically mediated conditions, today announced financial results for the quarter and year ended December 31, 2020, as well as business highlights.

“We made significant progress in the PRISM trial this year, despite the impact of COVID-19 which slowed recruitment activities worldwide through the latter part of 2020 and early 2021. Recruiting for this trial has accelerated this month and we expect to complete enrollment in the third quarter of this year and report top-line results in the fourth quarter of 2021,” said Jennifer L. Good, President and CEO of Trevi Therapeutics. “Throughout this past year, we have added to our key talent as we progress through the clinical development of Haduvio in two important indications and prepare for the next phase of development.”

Key Business Updates

- Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with prurigo nodularis (PN): To date, the Company has enrolled approximately 240 of the 360 planned total subjects in the trial and reaffirms expectations that enrollment will be completed in the third quarter of 2021 and top-line data will be reported in the fourth quarter of 2021.
- Phase 2 CANAL trial of Haduvio for chronic cough in patients with idiopathic pulmonary fibrosis (IPF): This trial is currently being conducted in the United Kingdom, which resumed its shelter in place directive due to COVID-19 in early December 2020 through the end of March 2021. The restrictions paused enrollment for this at-risk patient group during the related time period. We expect to resume recruiting subjects for the trial in the second quarter of 2021. Trevi is also seeking regulatory and ethics board approvals to add study sites in Germany.

Fourth Quarter 2020 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the fourth quarter of 2020 were $6.6 million compared to $4.8 million in the same period in 2019. The increase was primarily due to increased activity in the Company’s Phase 2b/3 PRISM clinical trial as well as expenses associated with the purchase of clinical trial supplies.

General and administrative (G&A) expenses: G&A expenses for the fourth quarter of 2020 were $2.6 million compared to $1.9 million in the same period in 2019. The increase was primarily due to an increase in consulting fees and stock-based compensation expenses.

Net loss: For the fourth quarter of 2020, the Company reported a net loss of $9.5 million, compared to a net loss of $6.5 million in the same period in 2019.

Year End 2020 Financial Highlights

Cash position: As of December 31, 2020, total cash and cash equivalents were $45.0 million compared to $57.3 million as of December 31, 2019. Trevi believes its current cash position will be sufficient to fund operations into the second quarter of 2022.

R&D expenses: R&D expenses for the year ended December 31, 2020 were $22.3 million compared to $19.3 million for the year ended December 31, 2019. The increase was primarily due to an increase in clinical development expenses, primarily related to increased activity and enrollment in the Phase 2b/3 PRISM trial as well as an increase in expenses related to the purchase of clinical trial supplies.

G&A expenses: G&A expenses for the year ended December 31, 2020 were $10.2 million compared to $7.3 million for the year ended December 31, 2019. The increase was primarily due to an increase in stock-based compensation expenses attributable to the issuance of new stock option grants in connection with the IPO and in the first quarter of 2020, increased consulting fees as well as increased expenses related to being a public company.

Net loss: For the year ended December 31, 2020, Trevi reported a net loss of $32.8 million compared to a net loss of $26.1 million for the year ended December 31, 2019.

Conference Call
As previously announced, the Company will host a conference call and webcast today, March 25, 2021 at 4:30 p.m. ET. To participate in the live conference call by phone, please dial (866) 360-5746 (domestic) or (602) 563-8605 (international) and provide access code 8599904. 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

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 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 and is in the planning stages of a Phase 2 study in this indication. 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 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. Trevi intends to propose Haduvio as the trade name for the nalbuphine ER investigational product. Haduvio is an investigational drug product and its safety and efficacy have not been fully 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 inherent in estimating Trevi's cash runway, future expenses 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, 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)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 45,001	$ 57,313
Working capital	40,714	54,353
Total assets	47,131	60,001
Total debt	13,954	—
Stockholders' equity	27,282	54,545

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Selected Statement of Operations Data

(unaudited)

(amounts in thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 6,560	$ 4,823	$ 22,328	$ 19,339
General and administrative	2,633	1,943	10,161	7,306
Total operating expenses	9,193	6,766	32,489	26,645

Loss from operations	(9,193)	(6,766)	(32,489)	(26,645)
Other income (expense), net	(313)	225	(287)	577
Loss before income tax benefit	(9,506)	(6,541)	(32,776)	(26,068)
Income tax benefit (expense)	(17)	4	18	18
Net loss	$ (9,523)	$ (6,537)	$ (32,758)	$ (26,050)

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