Trevi Therapeutics Announces Third Quarter 2022 Financial Results and Provides Business Update

Management to host a conference call and webcast today at 4:30 p.m. EDT

NEW HAVEN, Conn., Nov. 10, 2022 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of chronic cough in adults with idiopathic pulmonary fibrosis (IPF) and other chronic cough indications, and for the treatment of prurigo nodularis, today announced financial results for the quarter ended September 30, 2022, as well as provided business updates.

"I am incredibly proud of the progress our team has made this year with two positive data read-outs in our indications and subsequent successful financings," said Jennifer Good, President and CEO of Trevi Therapeutics. "At our R&D Day in September, we announced the final positive results from our Phase 2 CANAL trial of Haduvio for the treatment of chronic cough in IPF that demonstrated a strong magnitude of effect on cough and statistically significant data for the primary efficacy endpoint and other key secondary endpoints. We have approximately $126 million in cash, cash equivalents, and investments at the end of the quarter, which we plan to use to fund further development in our targeted cough indications."

Key Business Updates

Phase 2 CANAL trial of Haduvio for the treatment of chronic cough in IPF
As previously announced, the Phase 2 CANAL trial results from the full analysis set (N=38) achieved statistical significance on the trial's primary endpoint and showed Haduvio subjects had a 75.1% reduction in daytime cough frequency at the end of the treatment period vs. study baseline, compared to placebo subjects who had a 22.6% reduction, a 52.5% placebo-adjusted change ($p<0.0001$). The primary endpoint was supported by key secondary patient and clinician-reported outcomes. The safety results of the trial were generally consistent with the known safety profile of nalbuphine ER from previous trials. IPF is a serious, end-of-life disease, and chronic cough is a major cause of morbidity, significantly impacting these patients' quality of life.

Phase 2b/3 PRISM trial of Haduvio
We are continuing the open-label extension portion of our Phase 2b/3 PRISM trial for the treatment of prurigo nodularis, which we expect to complete in the first quarter of 2023. We plan to request an end of phase 2 meeting with the U.S. Food and Drug Administration in the first quarter of 2023.

Third Quarter 2022 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the third quarter of 2022 were $5.8 million compared to $4.7 million in the same period in 2021. The increase was primarily due to startup activities for our planned trials including purchases of clinical trial supplies and increased costs associated with increased activity in our Phase 2 CANAL trial as compared to the third quarter of 2021. This was offset by a reduction in costs associated with decreased activity in our Phase 2b/3 PRISM trial due to the completion of the blinded portion of the trial in the second quarter of 2022.

General and administrative (G&A) expenses: G&A expenses were $2.6 million in the third quarter of 2022 compared to $2.2 million in the same period in 2021. The increase was primarily due to higher legal fees associated with intellectual property filings and increased market research costs.

Net loss: For the third quarter of 2022, the Company reported a net loss of $8.3 million, compared to a net loss of $7.3 million in the same period in 2021. The increase was primarily due to the increase in R&D expenses.

Conference Call/Webcast
To participate in the live conference call by phone, please dial (888) 317 6003 (domestic) or (412) 317 6061 (international) and provide access code 4950734. 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.

Upcoming Meetings
The Company plans to participate at the following upcoming conferences and events:

- November 16: Stifel 2022 Healthcare Conference

- November 23: British Thoracic Society Winter Meeting 2022

About Chronic Cough in Idiopathic Pulmonary Fibrosis
IPF is a serious, end-of-life disease, and chronic cough is a major cause of morbidity, significantly impacting these patients' quality of life. There are estimated to be 140,000 IPF patients in the US and more than 1 million patients outside the US. Up to 85% of IPF patients experience chronic cough. There are no approved therapies for the treatment of chronic cough in IPF and the cough often isn't affected by antitussive therapy. Patients with chronic cough in IPF can cough up to 1,500 times per day, leading to increased feelings of fear and stress as it causes shortness of breath. Coughing spells or episodes lead to significant fatigue, an urge to breathe, low levels of oxygen in the blood, and some patients also experience loss of bladder control. The social impact of chronic cough in IPF is increased because of limited exercise ability, reduced walking distance, and the need for additional oxygen. Chronic cough in IPF may be an early clinical marker of disease activity that could potentially help to identify patients at high risk of progression and predict time to death or lung transplant. In addition, chronic cough in IPF may also contribute to enhanced activation of profibrotic mechanisms and disease worsening.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of chronic cough in adults with idiopathic pulmonary fibrosis (IPF) and other chronic cough indications, and for the treatment of prurigo nodularis. The Company has successfully completed a Phase 2 trial of Haduvio for the treatment of chronic cough in adults with idiopathic pulmonary fibrosis (IPF). Based on this positive data, Trevi plans to focus future clinical development on chronic cough conditions, including IPF, refractory chronic cough, and interstitial lung diseases (ILDs).

For more information, visit www.TreviTherapeutics.comand follow the Company on Twitter and LinkedIn.

About Haduvio
Haduvio, an investigational therapy, is an oral extended-release (ER) 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 centrally and peripherally active and known to be critical mediators of cough and itch. 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. Parenteral nalbuphine is not currently scheduled as a controlled substance by the DEA in the United States or by regulatory authorities in most of Europe. Trevi intends to propose Haduvio as the trade name for nalbuphine ER. 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 Trevi's business plans and objectives, including future plans or expectations for Haduvio and plans with respect to future clinical trials, 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; the risk that positive data from a clinical trial may not necessarily be predictive of the results of future clinical trials in the same or a different indication; uncertainties regarding Trevi's ability to execute on its strategy; uncertainties with respect to regulatory authorities' views as to the data from Trevi's clinical trials and next steps in the development path for Trevi's Haduvio in the United States and foreign countries; uncertainties inherent in estimating Trevi's cash runway, future expenses and other financial results, including Trevi's ability to fund future operations, including 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; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended September 30, 2022 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)

	September 30,	**December 31,**

	2022	2021
Cash and cash equivalents	$ 46,574	$ 36,830
Marketable securities	59,029	—
Working capital	112,677	25,233
Total assets	128,361	38,475
Total debt	10,800	14,485
Stockholders' equity	109,903	17,075

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 5,769	$ 4,718	$ 15,517	$ 16,805
General and administrative	2,636	2,229	7,733	7,398
Total operating expenses	8,405	6,947	23,250	24,203
Loss from operations	(8,405)	(6,947)	(23,250)	(24,203)
Other income (expense), net	132	(306)	(413)	(1,232)
Loss before income taxes	(8,273)	(7,253)	(23,663)	(25,435)
Income tax benefit (expense)	7	(2)	16	15
Net loss	$ (8,266)	$ (7,255)	$ (23,647)	$ (25,420)
Basic and diluted net loss per common share outstanding	$ (0.12)	$ (0.34)	$ (0.44)	$ (1.25)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	68,898,810	21,607,979	53,221,949	20,390,852

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