November 4, 2019

Trevena Reports Third Quarter 2019 Results and Topline Data From Multi-Dose Healthy Volunteer QT Study

Company expects to resubmit NDA for oliceridine in Q1 2020

Acute migraine proof-of-concept study for TRV250 initiated

Company to host conference call at 8:30 a.m. EST

CHESTERBROOK, Pa., Nov. 04, 2019 (GLOBE NEWSWIRE) -- **Trevena, Inc. (Nasdaq: TRVN)**, a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with central nervous system (CNS) disorders, today announced topline results from its multi-dose QT study for IV oliceridine, reported its financial results for the third quarter ended September 30, 2019, and provided an overview of its recent operational highlights.

“We believe the information provided from the multi-dose QT study thoroughly addresses the questions FDA posed to us. The results show no evidence of an accumulating effect of oliceridine on the QT interval, when administered in repeated doses to the 27 mg proposed maximum daily dose over 24 hours,” said Mark Demitrack, M.D., SVP and Chief Medical Officer. “These data, alongside the cardiac safety data submitted in the original NDA, provide a comprehensive assessment of the safety and tolerability of oliceridine, and will allow us to move ahead with plans for NDA resubmission in the first quarter of next year.”

Recent Corporate Highlights:

- **Completed multi-dose QT study for oliceridine.** No accumulation of effect was observed on the QT interval. A small, transient effect, consistent with that observed in the single-dose QT study, began dissipating after 12 hours and was absent at the end of the 24-hour study period despite repeated dosing of oliceridine.

  Oliceridine was well tolerated, with 59 subjects receiving the 27 mg maximum daily dose. There were no serious adverse events.

  In addition to this data, the Company previously announced that it has completed the work to address the other items requested by FDA in their complete response letter (CRL) for oliceridine. The Company expects to resubmit the NDA for oliceridine in the first quarter of 2020.

- **Initiated TRV250 acute migraine proof-of-concept study**. This is a single-dose, double-blind, placebo-controlled study with an enrollment target of approximately 120 migraine patients in a validated nitroglycerin (NTG) provocation migraine model.

Patients will be randomized before receiving a continuous NTG infusion, followed by administration of a 20 mg subcutaneous dose of TRV250 or placebo.

The primary objective of the study is to determine target engagement, which will be measured as a reduction of sustained NTG-induced headaches. This study will also evaluate the overall safety of TRV250 and its ability to reduce symptomatic anxiety. The Company anticipates reporting topline data from this study in the second half of 2020.

"With the completion of the multi-dose QT study, we have concluded all the necessary activities to address FDA's questions in the CRL for oliceridine. We remain on track to resubmit the NDA for oliceridine in the first quarter of next year," said Carrie Bourdow, President and Chief Executive Officer. "I am also very pleased that we continue to advance our pipeline with initiation of the acute migraine proof-of-concept study for TRV250."

Financial Results for Third Quarter 2019

For the third quarter of 2019, the Company reported a net loss attributable to common stockholders of $8.6 million, or $0.09 per share, compared to $4.5 million, or $0.06 per share, for the third quarter of 2018. This increase is primarily due to increased research and development expenditures in connection with our healthy volunteer QT study.

Cash, cash equivalents, and marketable securities were $44.7 million as of September 30, 2019. The Company believes its cash, cash equivalents, and marketable securities as of September 30, 2019, together with interest thereon, to be sufficient to fund the Company's operating expenses, debt service, and capital expenditure requirements into the third quarter of 2020.

Conference Call and Webcast Information

The Company will host a conference call and webcast with the investment community on November 4th, 2019 at 8:30 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and Chief Executive Officer, Barry Shin, SVP and Chief Financial Officer, and Mark Demitrack, SVP and Chief Medical Officer.

Live Call: Toll-Free: (855) 465-0180
International: (484) 756-4313

Webcast: investors.trevena.com

Replay: Toll-Free: (855) 859-2056
International: (404) 537-3406
Conference ID: 5249124
(Available approximately one hour after the completion of the live call until 11:59 p.m. ET on November 11, 2019)

About the Oliceridine Multi-Dose QT Study

This was a randomized, single-site, placebo- and positive-controlled three-period crossover study conducted in 68 healthy volunteers, with 59 subjects receiving the maximum daily

dose of 27 mg of IV oliceridine. The protocol and statistical analysis plan were developed based on review and feedback from FDA. The goal of the study was to collect the additional QT interval data requested by FDA for the resubmission of the NDA for oliceridine.

Subjects were randomly sequenced through all three study periods: IV oliceridine, placebo, and a single oral 400 mg moxifloxacin dose as a positive control. For the oliceridine and placebo arms, 2 or 3 mg of study drug or volume-matched placebo was administered by IV bolus every two hours over a 24-hour period. Electrocardiograms for all subjects were obtained at hourly timepoints using continuous Holter monitoring.

Oliceridine was well tolerated; adverse events were generally mild to moderate in severity and consistent with adverse events observed in the prior safety database. There were no serious adverse events.

The primary endpoint was the placebo-corrected change from baseline in the individual rate-corrected QT interval ($\Delta\Delta$QTcI) measured hourly at each of the 24 time points in the study. On this outcome, the mean $\Delta\Delta$QTcI was less than 10 msec at 22 of the 24 time points. The peak mean $\Delta\Delta$QTcI was observed at 9 hours and was 11.7 msec, with a 90% two-sided confidence interval upper bound of 14.7 msec at this time point. At 18 of the 24 measured timepoints, the upper bound of the 90% confidence intervals for the mean $\Delta\Delta$QTcI was less than 10 msec.

Secondary endpoints included the 24-hour time-weighted average $\Delta\Delta$QTcI and categorical analyses of clinically significant individual outliers. The 24-hour time-weighted average $\Delta\Delta$QTcI for oliceridine was 4.0 msec (90% two-sided CI=2.29, 5.78). There were no individual outliers with a rate-corrected change from baseline >60 msec or an absolute QT interval >500 msec.

About Oliceridine

Oliceridine is a G protein biased (selective) mu-opioid receptor ligand in development for the management of moderate-to-severe acute pain in hospitals or other controlled clinical settings where intravenous therapy is warranted. It is a new chemical entity with a novel mechanism of action that enables more selective targeting of newly discovered pathways with the potential for fewer side effects. Oliceridine is an investigational product and has not been approved by the FDA or any other regulatory agency. If approved, the Company expects that oliceridine will be classified as a Schedule II controlled substance.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with CNS disorders. The Company has four novel and differentiated investigational drug candidates, including IV oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the acute treatment of migraine, and TRV734 for maintenance treatment of opioid use disorder. The Company has also identified TRV045, a novel S1P receptor modulator that may offer a new, non-opioid approach to managing chronic pain.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of its therapeutic candidates, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the status, timing, costs, results and interpretation of the Company's clinical trials or any future trials, including with respect to any future clinical study of oliceridine; the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals, including the Company's assessment of the discussions with FDA, and whether there is a path to resubmit the oliceridine NDA; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and whether cash, cash equivalents, and marketable securities as of September 30, 2019 will be sufficient to fund operating expenses and capital expenditure requirements into the third quarter of 2020; uncertainties related to the Company's intellectual property; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates; and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments may cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as may be required by law.

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TREVENA, INC.
Condensed Statements of Operations
(Unaudited, in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**

Revenue	$ -	$ 3,000	$ -	$ 5,500
Operating expenses:				
General and administrative	3,201	3,908	9,572	14,906
Research and development	5,554	3,350	10,430	13,076
Restructuring charges	-	-	-	64
Impairment of property and equipment	-	-	108	-
Total operating expenses	8,755	7,258	20,110	28,046
Loss from operations	(8,755)	(4,258)	(20,110)	(22,546)
Other income	189	(225)	1,684	483
Loss before income tax expense	(8,566)	(4,483)	(18,426)	(22,063)
Foreign income tax expense	-	-	-	(745)
Net loss	$ (8,566)	$ (4,483)	$ (18,426)	$ (22,808)
Per share information:				
Net loss per share of common stock, basic and diluted	($0.09)	($0.06)	($0.20)	($0.32)
Weighted average shares outstanding, basic and diluted	92,569,993	77,445,675	91,307,429	70,604,827

TREVENA, INC.
Condensed Balance Sheets
(Unaudited, in thousands)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 29,255	$ 32,892
Marketable securities	15,461	28,590
Prepaid expenses and other current assets	2,329	607
Total current assets	47,045	62,089
Restricted cash	1,308	1,303
Property and equipment, net	2,848	3,387
Right-of-use lease assets	5,552	-
Other assets	18	-
Total assets	$ 56,771	$ 66,779
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,075	$ 1,416
Accrued expenses and other current liabilities	2,380	3,295
Current portion of loans payable, net	8,158	12,562
Current portion of lease liabilities	600	10

Deferred rent	-	207
Total current liabilities	14,213	17,490
Loans payable, net	-	4,811
Leases, net of current portion	7,968	20
Deferred rent, net of current portion	-	2,931
Warrant liability	6	1
Total liabilities	22,187	25,253
Common stock	92	82
Additional paid-in capital	441,187	429,727
Accumulated deficit	(406,700)	(388,274)
Accumulated other comprehensive income (loss)	5	(9)
Total stockholders' equity	34,584	41,526
Total liabilities and stockholders' equity	$ 56,771	$ 66,779

Source: Trevena Inc.