August 28, 2019

Trevena Advances NDA Resubmission Activities for Oliceridine

— Completed enrollment in healthy volunteer QT study, topline data expected in Q4 2019 —

— Completed *characterization of inactive metabolite* —

— Remains on track to resubmit NDA in Q1 2020 —

CHESTERBROOK, Pa., Aug. 28, 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) conditions, today provided an update on the activities to support resubmission of the New Drug Application (NDA) for oliceridine.

The Company has completed enrollment for the ongoing healthy volunteer QT study and remains on track to support topline data readout in the fourth quarter of 2019.

In addition, the Company has completed the necessary nonclinical work to further characterize the 9662 inactive metabolite. As agreed to with FDA, the Company has generated reproducible pharmacokinetic data using validated bioanalytical methods that demonstrate acceptable levels of exposure to the metabolite in nonclinical species.

Lastly, the Company has finished the outstanding drug product validation reports identified in the Complete Response Letter (CRL), which will be included in the NDA resubmission package.

"We continue to make steady progress on all fronts to gather the information needed to resubmit the NDA for oliceridine," said Carrie Bourdow, President and Chief Executive Officer. "I am pleased that we have finished the work to address three of the four items outlined in the CRL. Once we receive topline data for the healthy volunteer QT study, which we are on schedule to report next quarter, we look forward to resubmitting the NDA as early as possible in the first quarter of next year."

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with Central Nervous System conditions. 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, nonclinical studies, 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; 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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Source: Trevena Inc.