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Trevena Announces Initiation of Healthy Volunteer Study for Oliceridine

The Company remains on track to report topline data in Q4 2019

CHESTERBROOK, Pa., June 20, 2019 (GLOBE NEWSWIRE) -- **Trevena, Inc. (Nasdaq: TRVN)** ("Trevena" or the "Company"), a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with Central Nervous System conditions, announced today that it has initiated the healthy volunteer QT interval study for oliceridine, the Company's lead investigational drug candidate for the management of moderate to severe acute pain. The Company remains on track to report topline data in the fourth quarter of 2019 and currently expects to resubmit the New Drug Application (NDA) for oliceridine as early as possible in the first quarter of 2020.

"After receiving feedback from FDA on our proposed healthy volunteer study protocol and statistical analysis plan in mid-May, the team quickly finalized details to ensure a timely study start," said Carrie Bourdow, President and CEO. "I would like to commend the team for the considerable work they have accomplished to ensure that we reached this significant milestone on time, and we look forward to completing the critical work ahead for a successful resubmission of the oliceridine NDA."

The primary objective of the study is to collect the additional QT interval data requested by the U.S. Food and Drug Administration (FDA) for the resubmission of the NDA for oliceridine. The study will be performed in healthy volunteers at a single site as a three-period crossover design. Each subject will be randomly sequenced through all three study periods: oliceridine, placebo, and moxifloxacin as a positive control. A short, treatment-free washout occurs between each period. Electrocardiograms for all subjects will be obtained in a rigorous manner throughout the study. The Company plans to submit data on approximately 60 healthy volunteers, and among this study population, a minimum of 20 subjects will receive a cumulative dose of 27 mg, the proposed maximum daily dose of oliceridine.

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 and trials 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, whether there is a path to resubmit the oliceridine NDA, the timeline for NDA resubmission; available funding ; 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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