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# Trevena Announces Initiation of Proof-of-Concept Study for TRV734 for Potential Treatment of Opioid Use Disorder

CHESTERBROOK, Pa., Dec. 23, 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 the initiation of a proof-of-concept study for TRV734, the Company's novel mu-opioid receptor selective agonist. TRV734 is currently being evaluated as a potential maintenance therapy for opioid use disorder.

The study is funded by the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health. Trevena is providing TRV734 to NIDA Intramural Research Program scientists who are conducting the study.

"The opioid crisis remains a crippling public health issue, and multiple solutions are needed to tackle this urgent problem," said Carrie Bourdow, President and Chief Executive Officer of Trevena, Inc. "A novel mu-opioid receptor selective agonist such as TRV734 may have value as an alternative or complement to current treatments for opioid addiction, which are effective in some but not all people with opioid use disorder. We are excited to be working with NIDA to initiate this important proof-of-concept study."

This is a randomized, double-blind, four-period, placebo- and positive-controlled study that will enroll approximately 50 opioid-dependent patients undergoing stable methadone maintenance therapy. The primary objective of the study is to assess the ability of TRV734 to reduce acute opioid craving symptoms, as measured by the Subjective Opioid Withdrawal Scale. The study will also evaluate whether TRV734 suppresses withdrawal signs using the Clinical Opioid Withdrawal Scale. Secondary outcomes will include assessments of safety and measures of neurocognitive changes.

## About TRV734

TRV734 is a new chemical entity (NCE) targeting the same novel mechanism of action as Trevena's intravenous (IV) NCE, oliceridine, which selectively stimulates G-protein signaling at the mu-opioid receptor with low beta-arrestin recruitment. TRV734 was designed to be orally available, and its mechanism of action suggests it may offer valuable benefits for two distinct areas of important unmet medical need: pain and management of opioid dependence associated with opioid use disorder. Trevena is collaborating with NIDA to further evaluate TRV734 as a potential maintenance therapy for opioid use disorder. TRV734 is an investigational product not approved by FDA for distribution in the US.

## About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with Central Nervous System disorders.

The Company has four novel and differentiated investigational drug candidates, including IV olliceridine, 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 of any of the Company's investigational drug candidates; the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals, including the Company's assessment of the discussions with FDA; 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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