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Trevena Announces NIH Has Resumed Recruiting Patients in Proof-of-Concept Study for TRV734 in Opioid Use Disorder

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TRV734 reduced drug-seeking behavior in a preclinical model of relapse, suggesting its utility as a novel oral maintenance treatment for opioid use disorder

The study is being conducted and funded by the National Institute on Drug Abuse (NIDA), part of the NIH

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CHESTERBROOK, Pa., June 16, 2021 (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 that NIDA has resumed recruiting patients for its proof-of-concept study for TRV734, the Company's novel mu-opioid receptor selective agonist. The Company has an ongoing collaboration with NIDA to evaluate TRV734 as a potential maintenance therapy for opioid use disorder (OUD). The study was paused in March 2020 due to the global COVID-19 pandemic.

"Opioid use disorder remains an urgent public health issue – even as COVID-19 remains front of mind. It is important that the development of effective treatments for patients with opioid addiction continues," said Carrie Bourdow, President and Chief Executive Officer of Trevena, Inc. "NIDA's resumption of their study for TRV734, which may offer an effective treatment option with improved tolerability compared to current standard of care, underscores the unmet need for treatments for OUD. With this collaboration, we continue to build upon a robust partnership with NIH to explore several of our pipeline assets."

The NIDA study of TRV734 marks the third investigational drug product within Trevena's pipeline being researched by the NIH. 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 outcome is suppression of withdrawal 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, tolerability, and measures of neurocognitive changes.

About TRV734

TRV734 is an orally available new chemical entity that targets the mu-opioid receptor with a novel mechanism of action, which selectively stimulates G-protein signaling with low beta-

arrestin recruitment. In preclinical studies, TRV734 demonstrated similar analgesic effect with less constipation compared to equivalently analgesic doses of oxycodone and morphine. 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 innovative medicines for patients with CNS disorders. The Company has one approved product in the United States, OLINVYK® (oliceridine) injection, indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. The Company's novel pipeline is based on Nobel Prize winning research and includes four differentiated investigational drug candidates: TRV250 for the acute treatment of migraine, TRV734 for maintenance treatment of opioid use disorder, TRV045 for epilepsy and chronic neuropathic pain, and TRV027 for acute respiratory distress syndrome and abnormal blood clotting in COVID-19 patients.

For more information, please visit www.Trevena.com

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, commercialization of approved drug products and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "objective," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," "ongoing," or the negative of these terms or 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 commercialization of any approved drug product, 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 the FDA or other regulatory agencies about any and all of its programs; uncertainties related to the commercialization of OLINVYK; available funding; uncertainties related to the Company's intellectual property; uncertainties related to the ongoing COVID-19 pandemic, 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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