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Trevena Announces First Patient Enrolled in OLINVYK® Phase 3 Trial in China in Partnership with Jiangsu Nhwa Pharmaceutical

Nhwa is conducting and funding this study to support NDA regulatory filing in China

Trevena expects to receive approval and commercialization milestones, and a 10% royalty on net sales in China

CHESTERBROOK, Pa., July 08, 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 the Company's partner in China has enrolled the first patient in a Phase 3 trial for OLINVYK (oliceridine) injection, a novel IV analgesic approved in the U.S. by the Food and Drug Administration (FDA) for acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.

"We are committed to delivering OLINVYK to patients and healthcare providers in need of alternative acute pain treatment options, both through our ongoing launch in the U.S. as well as our global partnerships," said Carrie Bourdow, President and CEO of Trevena. "I am pleased that Nhwa has reached this important clinical development milestone, and we look forward to supporting their efforts to secure regulatory approval of OLINVYK in China."

This is a randomized, double-blind, active-controlled study that will enroll approximately 160 patients following abdominal surgery. The study includes an OLINVYK arm and an IV morphine positive control arm. The primary efficacy endpoint is the proportion of responders to study medication based on their pain numeric rating scale (NRS) at the end of the randomized 24-hour treatment period. Safety and tolerability will be assessed by respiratory depression adverse events (AEs), sedation AEs, the use of rescue antiemetics, clinician- and patient-reported satisfaction, and other measures. The study was developed based on feedback from the Chinese National Medical Products Administration (NMPA). Following study completion, Nhwa expects to have sufficient clinical data, accompanied by Trevena's existing clinical data, to submit OLINVYK for regulatory approval in China.

About OLINVYK® (oliceridine) injection

OLINVYK is a new chemical entity approved by the FDA in August 2020. OLINVYK contains oliceridine, a Schedule II controlled substance with a high potential for abuse similar to other opioids. It is indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. OLINVYK is available in 1 mg/1 mL and 2 mg/2 mL single-dose vials, and a 30 mg/30 mL

single-patient-use vial for patient-controlled analgesia (PCA). Approved PCA doses are 0.35 mg and 0.5 mg and doses greater than 3 mg should not be administered. The cumulative daily dose should not exceed 27 mg. Please see Important Safety Information, including the BOXED WARNING, and full prescribing information at www.OLINVYK.com.

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 diabetic neuropathic pain and epilepsy, and TRV027 for acute respiratory distress syndrome and abnormal blood clotting in COVID-19 patients.

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, the timing of FDA's decision on the oliceridine NDA; 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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