

Trevena Announces Wake Forest Baptist Health Joining OLINVYK® Clinical Outcomes Study

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Study is being led by Cleveland Clinic; designed to evaluate potential benefit of OLINVYK on respiratory, GI, and cognitive function outcomes in postoperative patients

Patient enrollment expected to begin in Q3 2021

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CHESTERBROOK, Pa., Aug. 25, 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 Wake Forest Baptist Health Medical Center will join the VOLITION ("Intravenous Oliceridine and Opioid Related Complications") study which examines the impact of OLINVYK (oliceridine) injection on respiratory, gastrointestinal (GI), and cognitive function outcomes in the postoperative setting. Ashish K. Khanna, FCCM, FCCP, M.D., Associate Professor of Anesthesiology, Wake Forest School of Medicine, will serve as the lead investigator at this hospital.

"I am pleased to welcome Wake Forest to our collaboration as we continue to strengthen the body of evidence underlying the unique clinical profile of OLINVYK," said Mark A. Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena. "We believe the safety and tolerability outcomes data that we will generate from this study will demonstrate additional areas of significant clinical need where OLINVYK may add value."

The VOLITION study is an open-label, multi-site study being led by clinical outcomes research experts from Cleveland Clinic. Respiratory safety will be assessed by continuous monitoring. Additional outcomes will include GI tolerability as measured by GI complete response, and cognitive function as measured by standardized somnolence, sedation, and delirium assessment scales. The study is expected to enroll approximately 200 adults undergoing major surgery. Patient enrollment is expected to begin in Q3 2021.

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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