July 7, 2021

# Trevena Announces Initiation of OLINVYK® Respiratory Physiology Study Including Elderly / Obese Subjects

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*Study is evaluating the role of age and weight in a comparative analysis of the effect of OLINVYK and morphine on respiratory function*

*Led by world-renowned research group, utilizing an innovative PK / PD clinical utility function analysis method*

*Enrollment expected to begin in Q3 2021; topline data expected by YE 2021*

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CHESTERBROOK, Pa., July 07, 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 it has initiated a new study evaluating the physiologic impact of OLINVYK on respiratory function in elderly / obese subjects.

This latest study is being led by Albert Dahan, M.D., Ph.D., Professor of Anesthesiology at the Leiden University Medical Center and a leading clinical researcher on the effects of opioid medications on respiratory physiology in humans. This study expands upon previously published work that the Company reported in collaboration with Dr. Dahan's research team. That work used clinical utility function analysis methodology based on the original OLINVYK Phase 1 ventilatory response to hypercapnia (VRH) data. Clinical utility function analysis is a novel method used in various scientific areas of research that integrates multiple physiologic inputs into a single integrated output function, as a method of estimated risk and benefit. In this study, the integrated inputs of interest are analgesia (benefit) and respiratory depression (risk).

"Clinical utility function analysis offers an objective and precise way to quantitatively assess the effect of different drugs on multiple outcomes, such as analgesia and respiratory depression, and thereby estimate relative benefit versus risk," said Dr. Dahan. "In my previous work using this framework, OLINVYK demonstrated a greater clinical benefit compared to IV morphine across clinically relevant plasma concentrations. I am pleased to have this opportunity to build upon this work and study OLINVYK in a population of individuals highly relevant to its use in clinical practice."

This is a Phase 1 randomized, double-blind, four-period crossover trial enrolling subjects ≥ 55 years old across a range of BMIs. The study aims to recruit ~50% of subjects who are ≥

65 years old and ~30% of subjects with a BMI > 30 kg/$m^2$. All subjects will receive two doses of OLINVYK and two doses of IV morphine to obtain a range of plasma concentrations that span the clinically relevant range for each medication. Respiratory depression will be assessed using the VRH measure, which is widely recognized as a precise method to assess respiratory physiology in humans. Analgesia will be measured using the cold pressor test, which is a valid and sensitive index of the pharmacologic effects of opioid agonists. The study will evaluate the ventilatory and analgesic effects of both treatments through population PK / PD modeling and clinical utility function analysis. Enrollment is expected to begin in Q3 2021, and the Company expects to report topline data by year-end 2021.

“I am pleased to be partnering again with Dr. Dahan as we continue to advance our post-approval clinical development plan for OLINVYK,” said Mark A. Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena, Inc. “Our goal is to continue strengthening the body of evidence underlying the differentiated clinical profile of OLINVYK, and we believe the physiologic data that will be generated by this innovative study will help to further elucidate OLINVYK’s therapeutic potential in the treatment of acute pain.”

**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.

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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Source: Trevena Inc.