

# Trevena, Inc. Announces Presentations at the Virtual 2020 American College of Clinical Pharmacology Annual Meeting

--

Live presentation highlighting TRV027 as a potential treatment for COVID-19 acute respiratory distress syndrome (ARDS) / abnormal clotting

Posters on OLINVYK benefit-risk profile and TRV250 Phase 1 pharmacokinetics

\_\_

CHESTERBROOK, Pa., Sept. 21, 2020 (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 three presentations at the virtual 2020 American College of Clinical Pharmacology (ACCP) Annual Meeting, taking place from September 21<sup>st</sup> to 23<sup>rd</sup>, 2020.

The Company will give a live presentation on TRV027, its AT<sub>1</sub> receptor selective agonist being studied as a potential treatment for ARDS / abnormal clotting in COVID-19. Additionally, the Company will present two posters highlighting previously published data for OLINVYK, which is approved in the U.S. for the management of acute pain, and TRV250, its delta receptor selective agonist being developed for the acute treatment of migraine.

"I am pleased at this opportunity to present compelling data from three of our programs. The interest from ACCP highlights the diversity of our novel pipeline, with multiple exciting catalysts over the next few months," said Mark A. Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena, Inc.

#### **Poster Presentation Details**

Live presentation: "The Use of Simulation in the Re-purposing of Drugs for COVID-19: The Example of TRV027" (8:00-9:30 a.m. ET, September 21<sup>st</sup>, 2020)

- In a COVID-19 infection, the SARS-coronavirus-2 binds to and removes the ACE2 protein in the lungs and other organs, resulting in a hormonal imbalance of angiotensin 2 within the RAAS pathway, converging at the AT<sub>1</sub> receptor.
- There is significant interest in the potential utility of TRV027 in COVID-19 patients, given its unique mechanism of action at the AT<sub>1</sub> receptor, which is known to mediate the effects of angiotensin 2 on lung damage and abnormal coagulation.

 Simulations were conducted to determine potential therapeutic doses, which informed a proof-of-concept trial recently initiated by Imperial College London. The study will enroll 60 hospitalized, non-ventilated patients aged 18 or older with a confirmed COVID-19 infection. The primary objective of the study is to evaluate whether TRV027 reduces abnormal clotting associated with COVID-19.

Poster presentation (#009): "Improved Safety of Opioid Analgesic Oliceridine Compared to Morphine Assessed by Utility Function Analysis" (4:00-6:00 p.m. ET, September 21 st and 22<sup>nd</sup>, 2020)

- OLINVYK was associated with a higher probability of analgesia than respiratory depression, while the reverse was true for morphine.
- The clinical utility function model predicted there would be a lower probability of a respiratory event occurring with OLINVYK versus morphine.
- Over the clinically relevant concentration range, OLINVYK had a higher probability of providing analgesia than producing respiratory depression, while morphine had a higher probability of producing respiratory depression than providing analgesia.

Poster presentation (#022): "A Phase 1 Healthy Volunteer Study of the Safety, Tolerability and Pharmacokinetics of TRV250, a G Protein-Selective Delta Receptor Agonist" (4:00-6:00 p.m. ET, September 21<sup>st</sup> and 22<sup>nd</sup>, 2020)

- TRV250 was well-tolerated up to 30 mg, with a PK profile appropriate for an acute migraine therapy.
- There were no serious adverse events and no clinically significant changes in EEG, ECG, or other safety parameters.

## About OLINVYK™ (oliceridine) injection

OLINVYK is a new chemical entity approved by the FDA in August 2020. 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 will not be available for distribution until the United States Drug Enforcement Administration assigns it to its schedule of controlled substances. Please see Important Safety Information, including the BOXED WARNING, and full prescribing information at <a href="https://www.olinvyk.com">www.olinvyk.com</a>.

#### **About TRV027**

TRV027 is a novel AT<sub>1</sub> receptor selective agonist that has previously been studied in 691 individuals. It has demonstrated efficacy, potency, and selectivity at the AT<sub>1</sub> receptor in nonclinical studies and has a well-characterized pharmacokinetic profile. In previous clinical trials, there was a low dropout rate associated with TRV027, and no significant safety issues were reported. In April 2020, the Company filed a provisional patent application with the United States Patent and Trademark Office covering the use of TRV027 to treat ARDS and the prevention or treatment of abnormal clotting in COVID-19 patients.

## **About TRV250**

TRV250 is a G-protein selective agonist targeting the delta receptor, with potential to be a first-in-class, non-narcotic mechanism for the treatment of migraine. TRV250 also may have utility in a range of other central nervous system indications. As a selective delta receptor modulator, TRV250 is not expected to have the abuse and addiction liability of medications targeting the mu opioid receptor. TRV250 is an investigational product and has not been 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 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 also has four novel and differentiated investigational drug candidates: TRV250 for the acute treatment of migraine, TRV734 for maintenance treatment of opioid use disorder, and TRV027 for acute lung injury / abnormal blood clotting in COVID-19 patients. The Company has also identified TRV045, a novel S1P receptor modulator that may offer a new, non-opioid approach to treating a variety of CNS disorders.

For more information, please visit <u>www.Trevena.com</u>

### **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 forwardlooking 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.

# For more information, please contact:

#### **Investor Contact:**

Dan Ferry Managing Director LifeSci Advisors, LLC <u>daniel@lifesciadvisors.com</u> (617) 430-7576

# **Company Contact:**

Bob Yoder SVP and Chief Business Officer Trevena, Inc. (610) 354-8840



Source: Trevena Inc.