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Trevena Announces Collaboration with Imperial College London to Evaluate TRV027 in COVID-19 Patients

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TRV027 is a novel AT₁ receptor selective agonist with the potential to treat acute lung injury and ARDS

Robust clinical development history with well-characterized PK and demonstrated safety in ~700 individuals

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CHESTERBROOK, Pa., June 02, 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 it has entered into a collaboration with Imperial College London to evaluate the potential of TRV027, a novel AT₁ receptor selective agonist, to treat acute lung injury contributing to acute respiratory distress syndrome (ARDS) in COVID-19 patients. ARDS is a major complication leading to mortality associated with COVID-19. Imperial College London will be sponsoring and funding this study, with additional support through the British Heart Foundation Centre for Research Excellence Award.

“It is a great privilege to be working with Imperial College London, a global thought leader in this pandemic, as we join the urgent fight to deliver treatments to healthcare providers and COVID-19 patients in dire need,” said Carrie Bourdow, President and Chief Executive Officer of Trevena, Inc. “TRV027 may offer a new and innovative approach to treating acute lung injury, which poses a grave threat to patients’ lives.”

“We are very pleased to be partnering with Trevena in our endeavor to combat the global threat posed by this pandemic,” said David Owen, M.D., Ph.D., Faculty of Medicine, Imperial College London and Head of Clinical Studies, Imperial Clinical Research Facility. “I am excited for this opportunity to study the potential utility of TRV027 in treating COVID-19 patients.”

In a COVID-19 infection, the SARS-coronavirus-2 binds to and removes the ACE2 protein in the lungs, causing elevated levels of angiotensin II. This drives overactivation of the AT₁ receptor, which results in downstream acute lung injury. This often develops into ARDS, which can ultimately lead to mortality. TRV027 potentially counteracts the disproportionate levels of angiotensin II, by competitively binding to and rebalancing AT₁ receptor activation. Additionally, its unique mechanism of action preferentially engages the signaling pathway to promote reparative effects on lung tissue.

TRV027 is an investigational new drug that has previously been studied in 691 individuals. It has demonstrated efficacy, potency, and selectivity at the AT₁ 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 in COVID-19 patients.

About the Imperial College London COVID-19 Study

This will be a randomized, double-blind, placebo-controlled Phase 1b proof-of-concept study in approximately 60 hospitalized, non-ventilated patients aged 65 or older with a confirmed or suspected COVID-19 infection. The study will determine whether TRV027, a novel AT₁ receptor selective agonist, modulates pathways that contribute to COVID-19 pathology. The primary endpoint is a coagulation cascade biomarker, which serves as a surrogate for measuring the effect of TRV027 on adverse health outcomes associated with increased mortality in COVID-19 infections. Imperial College London will be sponsoring and funding this study, with additional support through the British Heart Foundation Centre for Research Excellence Award.

About TRV027

TRV027 is a novel AT₁ receptor selective agonist. It is an investigational new drug that was studied through a Phase 2b trial for acute heart failure. TRV027 is currently being investigated as a potential treatment for acute lung injury contributing to ARDS in COVID-19 patients. TRV027 may counteract overactivation of the AT₁ receptor caused by SARS-coronavirus-2, while simultaneously promoting reparative effects on lung tissue. The use of TRV027 in COVID-19 patients has been proposed by Nobel Laureate Robert J. Lefkowitz, M.D., and Howard A. Rockman, M.D., both Professors of Medicine at Duke University and scientific co-founders of the Company, along with two of their colleagues, Laura M. Wingler, Ph.D., Duke University and Aashish Manglik, M.D., Ph.D., University of California San Francisco.

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 five novel and differentiated investigational drug candidates, including IV oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the acute treatment of migraine, TRV734 for maintenance treatment of opioid use disorder, and TRV027 for acute lung injury 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.

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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