July 8, 2013

Journal of Clinical Pharmacology Publishes First Clinical Experience with Trevena's Heart Failure Biased Ligand TRV027

KING OF PRUSSIA, Pa., July 8, 2013 /PRNewswire/ -- Trevena, Inc. (Trevena), a clinical stage pharmaceutical company and the leader in the discovery of G-protein coupled receptor (GPCR) biased ligands, today announced the electronic publication of Trevena's manuscript, "First Clinical Experience with TRV027: Pharmacokinetics and Pharmacodynamics in Healthy Volunteers." The manuscript can be viewed online at the Journal of Clinical Pharmacology's website (**http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1552-4604/earlyview**).

TRV027 is an experimental intravenous drug now in mid-stage clinical trials for the treatment of acute heart failure (AHF). The printed manuscript will appear in a future print issue of the journal. David G. Soergel, M.D., Trevena's Senior Vice President of Clinical Development, Jonathan D. Violin, PhD, Director of Biology and Co-Founder of Trevena, and Michael W. Lark, PhD, Trevena's Chief Scientific Officer and Senior Vice President of Research at Trevena, were among the publication's authors.

The manuscript summarizes results from the first-in-human clinical study in which the compound was administered to healthy human subjects. In this study, the tolerability, pharmacokinetics and pharmacodynamics of multiple doses of TRV027 were explored. TRV027 was safe and well-tolerated, with a usefully short half-life and dose-proportional increases in systemic exposure. The compound showed a decrease in mean arterial pressure in subjects that had an elevation in their renin angiotensin aldosterone system, a common characteristic in AHF patients. TRV027's activity, observed in the study, is consistent with its mechanism of action and previously published preclinical findings.

"In this phase 1 study, we successfully translated the unique activity profile of TRV027 from preclinical species into humans. These data supported our decision to progress TRV027 into Phase 2 studies in heart failure patients," commented Dr. Soergel.

About TRV027 and AHF

TRV027 is a novel beta-arrestin biased ligand of the angiotensin II type 1 receptor (AT1R) that combines the proven benefits of angiotensin blockade with new beta-arrestin-mediated biology to preserve cardiac and renal function. TRV027 is being developed by Trevena under a recently announced collaborative licensing option agreement with Forest Laboratories Inc. For more details, please find a copy of the May 9, 2013 press release on the Trevena website, under the "News" tab (**http://www.trevenainc.com/**).

In March 2013, Trevena also presented the results of a Phase 2a study on the hemodynamic effects of TRV027 in patients with advanced systolic heart failure as a poster at the annual American College of Cardiology meeting. Completion of the ascending dose-titration Phase 2a study was announced in October 2012, in which the safety, tolerability, pharmacokinetics, and invasive hemodynamics of TRV027 (formally TRV120027) was measured (NCT01187836). The drug was generally well-tolerated and produced a beneficial set of hemodynamic effects in the study. A phase 2b clinical trial of TRV027 is expected to begin later this year.

The American Heart Association estimated that AHF hospitalization costs the U.S. healthcare system more than $20 billion each year in direct spending. AHF is already the leading reason for hospitalization of individuals over 65 years old in the United States, with over 1 million hospital admissions per year. AHF is also the most costly diagnosis for Medicare in the nation. Despite the significance of this problem, current therapies are not producing meaningful improvements in patient outcomes. AHF incidence is increasing globally, and both heart failure mortality and hospital re-admission following an AHF event remain extremely high.

About Trevena

Trevena, Inc. is dedicated to discovering and developing the next generation of GPCR targeted medicines. GPCRs are the targets for at least one-third of modern medicinal products, and remain the predominant class of targets under clinical evaluation. Trevena's expertise lies in engineering "biased ligands" that activate only the beneficial signaling pathways downstream of a GPCR to unlock new biology and avoid drug adverse effects. In addition to TRV027, Trevena's pipeline currently includes a clinical stage mu-opioid biased ligand for post-operative pain, and discovery-stage programs for chronic pain and Parkinson's disease.

For more information, please contact:
Ros Deegan, VP Business Development, Trevena Inc., 610-354-8840 x225 (Corporate Inquiries)
Kimberly Minarovich, Christensen, 917-533-3268 (Media Inquiries)

SOURCE Trevena, Inc.