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Trevena to present results of TRV027 Phase 2a Study in Patients with Advanced Heart Failure

Poster at 2013 ACC Meeting describes the safety and anticipated pharmacology of TRV027 in patients with advanced heart failure

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)-- Trevena, Inc., the leader in the discovery and development of G-protein coupled receptor (GPCR) biased ligands, announced today that David Soergel, M.D., SVP of Clinical Development, will present the results of a Phase 2a study on the hemodynamic effects of TRV027 in patients with advanced heart failure with reduced ejection fraction, as a poster at the American College of Cardiology meeting, to be held in San Francisco on March 9th through 11th, 2013. The poster will be presented on Sunday, March 10th.

Trevena successfully completed the Phase 2a study in October 2012, in which TRV027 was generally well-tolerated and produced a beneficial set of hemodynamic effects. Trevena is developing TRV027 for the intravenous hospital treatment of acute decompensated heart failure (ADHF), and the data being presented supports the advancement of TRV027 into further studies. A Phase 2b study to evaluate its clinical efficacy in patients with ADHF is currently being planned.

The completed Phase 2a study is a randomized, double-blind, placebo-controlled, adaptive, ascending dose-titration study to evaluate the safety, tolerability, pharmacokinetics, and invasive hemodynamics of TRV027 in patients with stable NYHA Class 3 and 4 heart failure (**NCT01187836**). Thirty-three catheterized patients were enrolled at centers in the US and Europe. Twenty-four patients received TRV027 and 9 patients received placebo.

“Significantly, in this study we have been able to safely reproduce the unique preclinical pharmacology of TRV027 in patients with heart failure,” commented Maxine Gowen Ph.D., Trevena President and CEO. “TRV027 is the lead asset in our biased ligand portfolio, and we are delighted that these results support its progression to a proof-of-concept study in ADHF.”

TRV027 is an intravenous biased ligand at the Angiotensin II type 1 receptor (AT1R), which is the same target inhibited by the oral ARBs, that are successfully used as chronic daily therapy to slow the progression of heart failure. Because it is a biased ligand however, TRV027 not only brings the benefits of AT1R blockade in heart failure to the acute setting, but also unlocks direct cardiac benefits mediated by beta-arrestin. The unique mechanism of this novel molecule has been previously highlighted in several publications, including articles in Circulation Heart Failure and the American Journal of Physiology.

About ADHF

ADHF represents a serious challenge for patients, physicians and healthcare systems. The American Heart Association estimated that ADHF hospitalization costs the U.S. healthcare system more than $20 billion each year in direct spending. ADHF 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. ADHF is also the most costly diagnosis for Medicare. Despite the significance of this problem, current therapies are not producing meaningful improvements in patient outcomes. ADHF incidence is increasing globally, and both heart failure mortality and hospital re-admission following an ADHF event remain extremely high. There is an urgent need for better treatments, and a clear incentive for regulators and payers to approve and reimburse them.

About Trevena and Biased Ligands

Trevena, Inc. is a clinical stage pharmaceutical company focused on discovering and developing the next generation of G-protein coupled receptor (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. Trevena is based in King of Prussia, Pennsylvania and is backed by leading investors including Alta Partners, Healthcare Ventures, NEA, Polaris and Yasuda Enterprise Development Company. For more information about the company, please visit www.trevenainc.com.

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