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Trevena Initiates Clinical Development of TRV120027, a First-in-Class Biased Ligand

Phase 1 Trial Launched to Evaluate Compound for the Treatment of Acute Decompensated Heart Failure

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)-- Trevena Inc., a leader in the discovery of G-protein coupled receptor (GPCR) biased ligands, today announced the initiation of a Phase I clinical trial of TRV120027, a titratable i.v. agent designed for the treatment of acute decompensated heart failure. TRV120027 is a biased ligand that targets the angiotensin II type 1 receptor (AT1R) and induces a unique mode of signaling. It simultaneously blocks angiotensin-mediated G-protein signaling while stimulating AT1R-specific b-arrestin signaling. In preclinical studies, this biased signaling has demonstrated a unique range of biological effects that are highly advantageous to patients with acute heart failure.

"TRV120027 is the first biased ligand to be discovered and tested in humans," stated Maxine Gowen, Ph.D., president and CEO of Trevena. "It is not only an exciting new approach to the treatment of acute heart failure, but represents the first of an entirely new class of agent targeting the most successful drug target family, the G-protein-coupled receptors (GPCRs). This next generation of safer and more efficacious GPCR drugs is the sole focus of Trevena's drug discovery engine, and we are excited to bring forward the first biased ligand agent into human trials."

The Phase 1 study of TRV120027 is a single-dose, dose escalation, crossover study in 2 cohorts of healthy subjects. The aims of the study are to assess the safety, tolerability and pharmacokinetics of TRV120027 when delivered as a 4-hour continuous infusion. In addition, exploratory measures of TRV120027's pharmacology are being performed. The results of this study will inform dose selection and dosing regimens for subsequent studies of TRV120027 in patients with heart failure.

"Acute heart failure is a major health problem worldwide, and despite advances in the treatment of chronic heart failure, no safe and effective new treatments have been introduced for many years," said David Soergel, M.D., vice president of clinical development at Trevena. "I am excited to be involved with such a promising new therapy that could provide great benefit to patients who currently have few effective options."

About Biased Ligands and TRV120027

With approximately 40% of modern medicinal products targeting GPCRs and GPCRs remaining the largest class of targets currently under clinical evaluation, this group comprises the most successful drug target class. However, traditional ligands either turn on or turn off all of the signaling pathways engaged by a particular receptor, which can result in limited efficacy and undesirable adverse effects. In contrast, Trevena's novel drug discovery approach is focused on discovering and developing a linked portfolio of GPCR ligands that

are "biased" toward either activating or blocking specific signaling pathways mediated through individual GPCRs. These biased ligands selectively turn on or off individual pathways, and in so doing provide an enhanced level of drug specificity. This specificity allows enhanced efficacy or decreased side effects to be designed into the drug candidate.

TRV120027 is a first-in-class agent that, due to its unique spectrum of biological effects, could provide a major advance in the treatment of acute heart failure. It targets AT1R, which plays a central role in the pathophysiology of heart failure. In a preclinical disease model of heart failure TRV120027 improves several of the key pathologies that are seen in heart failure in humans. Based on its profile in animals, TRV120027 is expected to rapidly provide symptomatic benefit while promoting an improvement in target organ function in patients suffering from acute heart failure.

About Trevena

Trevena, Inc. is a leader in the discovery and development of GPCR biased ligand drugs. Trevena combines a powerful and efficient drug discovery platform with extensive development experience to yield a rich linked portfolio of novel medicines. Trevena's proprietary Advanced Biased Ligand Explorer, or ABLE(TM), platform includes customized assays, proprietary software, animal models and unique biological signaling information across multiple GPCRs that allow for the discovery, optimization and development of unique biased ligands into differentiated new medicines. The company's drug discovery technology is based on extensive research from the laboratories of leading scientists in the GPCR field - Robert J. Lefkowitz, M.D. and Howard A. Rockman, M.D. of Duke University Medical Center. Trevena's pipeline is currently focused on programs for cardiovascular and CNS indications with significant unmet medical needs. Founded in 2008, Trevena is based in King of Prussia, Pennsylvania and is a privately held company backed by leading investors including Alta Partners, Healthcare Ventures, NEA, Polaris and Yasuda Economic Development Corporation. For more information about the company, please visit www.trevenainc.com.

Source: Trevena Inc.