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Trevena Announces Dosing of First Patient in Phase 2b BLAST-AHF Trial of TRV027 for Acute Heart Failure

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)-- Trevena, Inc., a clinical stage pharmaceutical company involved in the discovery and development of G-protein coupled receptor (GPCR) biased ligands, announced today initiation of dosing in BLAST-AHF, the Company's randomized, multi-center Phase 2b trial of TRV027 in patients with acute heart failure (AHF). TRV027 is a novel beta-arrestin biased ligand of the angiotensin II type 1 receptor that is being developed as a first-line intravenous treatment in combination with standard diuretic therapy for AHF patients. Trevena has granted Forest Laboratories (NYSE:FRX) an exclusive option to license TRV027 under the companies' May 2013 Option and Licensing Agreements.

"There is a significant need for new treatment options in acute heart failure, in particular for therapies that have an impact on the underlying biology of the heart failure syndrome itself. In some cases, existing treatments may actually perpetuate the underlying pathophysiology of the disease," stated Michael Felker M.D., chief of the heart failure section at the Duke University Medical Center, and scientific steering committee co-chair for this study. "TRV027 represents a promising approach for treating AHF in the hospital emergency department, with rapid onset, reversible effects on blood pressure, and specificity of its mechanism for the syndrome," added Peter Pang M.D., associate professor in emergency medicine and cardiology, Northwestern University Feinberg School of Medicine, and scientific steering committee co-chair for the study.

The randomized, double-blind, standard of care controlled, Phase 2b BLAST-AHF trial is designed to enroll at least 500 patients with AHF, and will compare TRV027 plus standard heart failure therapy versus placebo plus standard therapy. The primary objective of this trial is to evaluate the effects of three dose levels of TRV027, 1.0 mg/hr, 5.0 mg/hr and 25 mg/hr, on a composite of clinically important outcomes: mortality, worsening heart failure, hospital readmission rate, dyspnea, and length of hospital stay. In this study, TRV027 or placebo will be initiated soon after presentation to the hospital, and will then continue to be administered for a minimum of 48 hours and up to 96 hours.

"The initiation of BLAST-AHF represents another significant milestone in our efforts to rapidly translate our groundbreaking research on biased ligands into differentiated treatments with improved efficacy and safety profiles," stated Maxine Gowen, Ph.D., president and chief executive officer of Trevena. "With this study, we are building on earlier data demonstrating the potential of TRV027 to rapidly reduce blood pressure and, unlike current therapies, promote beneficial effects on the three key organ systems affected during acute heart failure – the blood vessels, kidneys and heart. We look forward to advancing the BLAST-AHF trial and expect data to be available in the second half of 2015."

About the Option and Licensing Agreements with Forest

In May 2013, Trevena entered into option and licensing agreements with Forest Laboratories, which granted Forest an exclusive option to license TRV027. The option may be exercised at any time before Trevena delivers the Phase 2b clinical trial results to Forest and during a specified period of time thereafter. If Forest exercises its option, the license agreement will become effective, and Forest will have an exclusive worldwide license to develop and commercialize TRV027 and specified related compounds. Forest will be responsible for subsequent development, regulatory approval and commercialization of TRV027. Under the agreement, Trevena could potentially receive up to $430 million in the aggregate, including an upfront option exercise fee of $65 million and milestone payments depending upon the achievement of future development and commercial milestones, as well as tiered royalties between 10% and 20% on worldwide net sales.

About Acute Heart Failure

There are over 20 million people living with heart failure in the United States and Europe, according to the American Heart Association and the European Society of Cardiology. Acute heart failure (AHF) is a worsening of the signs and symptoms of heart failure that typically requires hospitalization. The National Hospital Discharge Survey, or NHDS, in the United States reported over 5 million hospital discharges in 2010 where heart failure was listed as a component of the diagnosis, over 1 million of which listed heart failure as the primary diagnosis. The American Heart Association estimated that heart failure hospitalization costs the U.S. healthcare system more than $20 billion in 2009. Despite long hospital stays, approximately 50% of AHF patients are still symptomatic on discharge according to data from ADHERE, a national U.S. registry of over 100,000 AHF patients admitted to the hospital between 2000 and 2005. The readmission rate for heart failure is unacceptably high and there is an urgent need to develop new therapies that reduce patient rehospitalization and mortality.

About Trevena

Trevena, Inc. is a clinical stage biopharmaceutical company that discovers, develops and intends to commercialize therapeutics that use a novel approach to target G protein coupled receptors, or GPCRs. Using its proprietary product platform, Trevena has identified and advanced two differentiated product candidates into the clinic -- TRV027 to treat acute heart failure and TRV130 to treat moderate to severe acute pain intravenously. Trevena also plans to advance additional product candidates, including two preclinical programs focused on central nervous system indications.

About Forest Laboratories

Forest Laboratories' (NYSE: FRX) longstanding global partnerships and track record developing and marketing pharmaceutical products in the United States have yielded its well-established central nervous system and cardiovascular franchises and innovations in anti-infective, respiratory, gastrointestinal and pain management medicine. Forest’s pipeline, the most robust in its history, includes product candidates in all stages of development across a wide range of therapeutic areas. The Company is headquartered in New York, NY. To learn more, visit www.FRX.com.

Except for the historical information contained herein, this release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in Forest Laboratories' Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and any subsequent SEC filings. Forest assumes no obligation to update forward-looking statements contained in this release to reflect new information or future events or developments.

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