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## **Trevena completes interim analysis and announces plans for ongoing Phase 2b BLAST-AHF trial of TRV027 in acute heart failure**

**- Remaining enrollment weighted towards most promising dose -**

**- Actavis fully funds expansion of study -**

KING OF PRUSSIA, Pa.--([BUSINESS WIRE](#))-- Trevena, Inc. (NASDAQ: TRVN), a clinical stage biopharmaceutical company, today announced its plans for the continuation of the BLAST-AHF trial – a double-blind placebo-controlled study of TRV027 in patients with acute heart failure (AHF) – following the recent completion of the pre-specified interim analysis. Based on a review of the safety and efficacy data from 254 study patients, Trevena and Actavis have agreed to weight future enrollment toward the most promising dose and to increase target enrollment in the study from 500 patients to 620 patients. Actavis, which holds an exclusive option to license TRV027, will fully fund this expansion of the study via a \$10 million payment to Trevena.

The purpose of the planned interim analysis was to qualitatively and quantitatively evaluate safety and efficacy data to determine how best to allocate future patients in the study to generate the most robust data. Upon reviewing the data, the data safety monitoring board (DSMB) and the BLAST-AHF Steering Committee recommended that future enrollment be weighted to the most promising dose of 5 mg/hr. Remaining enrollment will be weighted 2:1:2:1 for placebo, 1 mg/hr, 5 mg/hr, and 25 mg/hr, respectively. In addition, the DSMB and Steering Committee determined that patients with lower baseline systolic blood pressure could safely enroll in the study; inclusion criteria have been modified accordingly. As a result of the increased target enrollment, Trevena now expects to release top-line data in the first half of 2016.

“While it is still early in the trial, we believe the trends in efficacy and safety at this interim stage are promising and suggest that TRV027 may have important clinical benefits in AHF,” stated David Soergel, M.D., Trevena’s chief medical officer. “As contemplated in the interim analysis plan, focusing future enrollment on the most promising dose enhances the trial’s power, and increasing the target enrollment should allow us to generate important additional dose ranging information to better plan Phase 3 development. In addition, the current data allow us to include AHF patients with lower systolic blood pressure for whom there are few proven therapeutic options.”

“We are encouraged by progress in the BLAST-AHF trial and are grateful to Actavis for their further investment in this important program,” said Maxine Gowen, Ph.D., Trevena’s CEO. “We look forward to working with Actavis to continue developing TRV027 as a potentially valuable new medicine for this devastating and challenging disease.”

**About the ongoing Phase 2b BLAST-AHF trial**

BLAST-AHF is a randomized, double-blind, standard of care controlled trial that will enroll approximately 620 patients with AHF. The study has compared TRV027 (1.0 mg/hr, 5.0 mg/hr and 25 mg/hr) plus standard heart failure therapy versus placebo plus standard therapy. The primary objective of this trial is to evaluate the effects of TRV027 on a composite of outcomes, each of which is clinically important: mortality, worsening heart failure, hospital readmission rate, dyspnea, and length of hospital stay. In this study, TRV027 or placebo is initiated after presentation to the hospital and then continued to be administered for a minimum of 48 hours and a maximum of 96 hours. Details of the trial design were published in January 2015 as a “state of the art” paper in the *Journal of the American College of Cardiology – Heart Failure*. Trevena expects to report data from this trial in the first half of 2016.

### **About TRV027**

TRV027 is an investigational peptide drug in a Phase 2b trial for the treatment of AHF. It targets the angiotensin II type 1 receptor, a key driver of AHF, with an innovative “biased ligand” mechanism that enhances cardiovascular performance. This profile suggests that TRV027 has the potential to become an important new therapy for AHF patients.

### **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 is developing four biased ligand product candidates that it has identified – TRV027 to treat acute heart failure (Phase 2b), TRV130 to treat moderate to severe acute pain intravenously (Phase 2b), TRV734 to treat moderate to severe acute and chronic pain orally (Phase 1), and TRV250 for treatment-refractory migraine (Preclinical).

### **Cautionary Note on 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 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, including which TRV027 dose is the most promising of the three doses tested to date and when data will be reported from the TRV027 Phase 2b trial; the uncertainties inherent in conducting clinical trials; whether interim results and trends from an ongoing clinical trial will be predictive of the

final results of the trial or results of early clinical trials will be indicative of the results of future trials, including whether TRV027 may show an important clinical benefit in AHF and become a valuable new medicine for AHF; expectations for regulatory approvals; availability of funding sufficient for the company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the company's therapeutic candidates; the inherent uncertainties associated with intellectual property; 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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