

Trevena, Inc. Announces Initiation of Oliceridine Phase 3 Clinical Program With Multi-Procedure Safety and Tolerability Study

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)-- Trevena, Inc. (NASDAQ:TRVN), a clinical stage biopharmaceutical company focused on the discovery and development of biased ligands targeting G protein coupled receptors, today announced the launch of the oliceridine (TRV130) Phase 3 clinical program with the enrollment of patients in the open label Phase 3 ATHENA-1 study. This study will evaluate the safety and tolerability of oliceridine in patients with acute moderate-to-severe pain in a variety of clinical settings.

ATHENA-1 is a Phase 3 open label, multicenter study evaluating the safety and tolerability of oliceridine in approximately 900 patients. The study will enroll eligible patients with moderate to severe pain caused by medical conditions or surgery. Patients will be treated with oliceridine on an as-needed basis via IV bolus, patient-controlled analgesia (PCA) administration, or both, as determined by the investigator. The primary objective is to assess the safety and tolerability of oliceridine. Pain intensity will be measured as a secondary endpoint.

The Company also announced that an End-of-Phase 2 meeting with FDA has been scheduled for later this quarter. In the second quarter, the Company expects to communicate additional details of its Phase 3 development program, including details of its pivotal studies of oliceridine in acute moderate-to-severe pain.

"We are pleased to announce the start of our Phase 3 program with the initiation of ATHENA-1, which will provide data on the safety profile of oliceridine in a wide range of settings," said Maxine Gowen, Ph.D., chief executive officer. "We also look forward to discussing the oliceridine Phase 3 program with the FDA later this quarter, and remain on track to file an NDA for oliceridine in the second half of 2017."

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 four biased ligand product candidates – TRV027 to treat acute heart failure (Phase 2b), oliceridine (TRV130) to treat moderate to severe acute pain intravenously (Phase 3), TRV734 to treat moderate to severe acute and chronic pain orally (Phase 1), and TRV250 for acute migraine and other CNS disorders (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: uncertainties related to the Company's intellectual property; the status, timing, costs, results and interpretation of the Company's clinical trials and the timing of the NDA filing for oliceridine; the uncertainties inherent in conducting clinical trials; whether interim results from a 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; expectations for regulatory approvals and for the timing and results of the End-of-Phase 2 meeting with the FDA; 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; 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20160119005256/en/

Investor:

Trevena, Inc.
Jonathan Violin, (610) 354-8840 x231
Director of Investor Relations
jviolin@trevenainc.com

Source: Trevena, Inc.