June 28, 2018

Trevena announces successful completion of Phase 1 study of TRV250 for acute migraine

– Pharmacokinetics, safety, and tolerability support advancement of TRV250 to Phase 2 –

– Data suggest potential for TRV250 to be the first selective delta receptor modulator –

CHESTERBROOK, Pa., June 28, 2018 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) announced today the successful completion of its first-time-in-human Phase 1 study of TRV250, a biased delta receptor agonist that the Company is developing for the treatment of acute migraine. Preclinical data suggested that the novel selective signaling mechanism of TRV250 might avoid the seizure liability that has limited development of therapeutics targeting the delta receptor. Data from this healthy volunteer study showed safety, tolerability, and pharmacokinetics supporting the advancement of TRV250 to Phase 2 proof of concept evaluation in patients.

Key findings of the study were as follows:

- Dose-related increases in plasma concentrations following subcutaneous administration of doses up to 30 mg, with rapid absorption in the first hour and duration of exposure appropriate for treating acute migraine;
- Subcutaneous doses at and above 9 mg achieved plasma concentrations that were active in preclinical models of migraine;
- Oral bioavailability similar to existing migraine medications, supporting continued development of TRV250 in oral and/or subcutaneous formulations;
- No observed drug-associated EEG changes, consistent with preclinical studies in which TRV250 avoided the seizure liability associated with previous CNS-active delta receptor agonists; and
- No clinically significant changes in vital signs, laboratory values, or ECG parameters, and no severe or serious adverse events reported.

“We are pleased that TRV250 continues to show great potential for the treatment of acute migraine,” said Maxine Gowen, President & CEO. “Even as the treatment landscape for chronic migraine has evolved, there remains an important unmet need for patients who continue to suffer acute migraines and cannot achieve relief with currently available options. With the exposures reached in this study without associated EEG changes, TRV250 may finally unlock the delta receptor as a therapeutic target, and we look forward to laying the groundwork for a future Phase 2 trial with this novel molecule.”

About the trial

This first-time-in-human study was a two part, randomized, single-blind, placebo-controlled,

single ascending dose study to evaluate the safety, tolerability, and pharmacokinetics of subcutaneous and oral TRV250 in healthy adult males and females. Part A assessed single subcutaneous doses in 38 healthy subjects. Four cohorts of 9 or 10 subjects were randomized to receive a single dose of up to 30mg TRV250 or placebo. Part B consisted of a single cohort of 9 subjects administered either TRV250 as a single 6 mg oral dose (either as a capsule in the fed state or a capsule in the fasted state, n=7) or placebo (as a capsule in the fed or fasted state, n=2).

About TRV250

TRV250 is a G protein biased ligand targeting the delta receptor, with potential to be a first-in-class, non-narcotic mechanism for the treatment of migraine. TRV250 also may have utility in a range of other central nervous system indications. As a selective delta receptor modulator, TRV250 is not expected to have the abuse and addiction liability of medications targeting the mu opioid receptor.

About Trevena

Trevena, Inc. is a biopharmaceutical company developing innovative therapies based on breakthrough science to benefit patients and healthcare providers confronting serious medical conditions. The Company has discovered four novel and differentiated drug candidates, including oliceridine injection, currently under review by the U.S. Food and Drug Administration for potential approval for the management of moderate-to-severe acute pain, TRV250 for the treatment of acute migraine, and TRV734 for pain. The Company maintains an early stage portfolio of drug discovery programs.

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 the results of the Company's Phase 1 study of TRV250 and whether such results support the advance of TRV250 into Phase 2, the potential of TRV250 for the treatment of acute migraine or of the delta receptor as a therapeutic target, and any plans for potential future clinical studies of this molecule; the uncertainties inherent in conducting clinical trials; expectations for regulatory approvals; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; uncertainties related to the Company's intellectual property; 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.

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