October 11, 2018

Trevena Announces Oliceridine FDA Advisory Committee Meeting Outcome

CHESTERBROOK, Pa., Oct. 11, 2018 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ: TRVN), today announced the outcome of the meeting of the U.S. Food and Drug Administration (FDA) Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) to review and discuss oliceridine. At the meeting, the Advisory Committee voted 8 against, and 7 in favor of, the approval of oliceridine for the management of moderate to severe acute pain in adult patients for whom an intravenous (IV) opioid is warranted.

“We continue to believe that the totality of evidence presented and discussed today supports the utility of oliceridine as a new analgesic option for the management of moderate to severe acute pain for patients in hospitals or other controlled clinical settings,” said Carrie L. Bourdow, President and Chief Executive Officer. “Trevena is committed to working closely with the FDA as they complete their review of the NDA for oliceridine.”

The Advisory Committee reviewed data from oliceridine’s full clinical development program with a focus on the Phase 3 APOLLO 1 and APOLLO 2 efficacy studies, as well as the Phase 3 ATHENA open-label safety study that was intended to emulate real world use of oliceridine in a broad spectrum of surgical and medical acute pain conditions. In controlled clinical trials, oliceridine demonstrated efficacy compared to placebo along with a safety and tolerability profile consistent with the class.

Trevena’s New Drug Application (NDA) submission for oliceridine was accepted for review by the FDA on January 2, 2018 with a Prescription Drug User Fee Act (PDUFA) target date for completion of review by the FDA of November 2, 2018. The FDA is not bound by the Advisory Committee's recommendations but takes its advice into consideration when making its decision.

About Oliceridine
Oliceridine is a G-protein biased mu-opioid receptor (MOR) ligand in development for the management of moderate to severe acute pain in hospitals or other controlled clinical settings and where intravenous (IV) therapy is warranted. It is a new chemical entity with a novel mechanism of action that enables more selective targeting of newly discovered pathways with the potential for fewer side effects. Oliceridine is an investigational product and has not been approved by the FDA or any other regulatory agency. If approved, the Company has requested that oliceridine be classified as a Schedule II controlled substance.

About Trevena
Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of new and innovative treatment options for patients in pain. The Company has discovered three novel and differentiated drug candidates using its proprietary platform, including intravenous (IV) oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the treatment of acute migraine, and TRV734 for pain

and/or management of opioid dependence. In its preclinical programs, Trevena is evaluating a set of novel S1P modulators that may offer a new, non-narcotic approach to managing chronic pain.

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 or any future trials, including with respect to the results of the Company's controlled clinical trials versus placebo and suggest that oliceridine may be effective and generally well-tolerated for patients with acute pain who require the use of IV opioids; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals, including with respect to the oliceridine NDA and the impact, if any, of the Advisory Committee recommendation on the FDA's decision regarding the NDA; 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.

Contacts

Trevena, Inc.

Investors:
Jonathan Violin, Ph.D.
Senior Vice President, Scientific Affairs & Investor Relations Officer
610-354-8840 x231
jviolin@trevena.com

or

Media:
Patrick Ryan
pryan@w2ogroup.com

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