February 22, 2016

Trevena, Inc. Receives FDA Breakthrough Therapy Designation for Oliceridine for the Management of Moderate-to-Severe Acute Pain

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 that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to the Company's lead product candidate, intravenous oliceridine (TRV130), for the management of moderate-to-severe acute pain. Following two successful Phase 2 studies, oliceridine is now in Phase 3 development. The ATHENA-1 safety and tolerability study is ongoing, with pivotal studies expected to begin in the second quarter of 2016.

“We are delighted that the FDA has chosen to grant Breakthrough Therapy designation to oliceridine,” said Maxine Gowen, Ph.D., chief executive officer. “There is an urgent need for a novel analgesic that delivers powerful pain relief with improved safety and tolerability. We believe this designation recognizes our promising Phase 2 study data for oliceridine, which showed encouraging differentiation from morphine. We look forward to working even more closely with the FDA to facilitate our development of oliceridine.”

Breakthrough Therapy designation is granted by the FDA to new therapies intended to treat serious conditions, and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. For oliceridine, the designation request included the full study results of both of the Company’s recent Phase 2 studies. Breakthrough Therapy designation provides all the benefits of the Fast Track program, as well as more intensive FDA guidance on preparing an efficient drug development program and eligibility for rolling review and priority review.

About oliceridine

Oliceridine (TRV130) was designed to optimize μ opioid receptor pharmacology to deliver an improved analgesic profile, and was previously granted Fast Track designation by the FDA. Oliceridine is the first μ receptor G protein pathway selective modulator (μGPS) – a biased μ opioid receptor ligand that in preclinical studies activated pathways associated with analgesia while avoiding pathways that can promote respiratory depression and gastrointestinal dysfunction and limit analgesia. In Phase 2, intravenous oliceridine demonstrated rapid and powerful analgesic efficacy with reduced frequency of opioid-related adverse events including nausea, vomiting, and hypoventilation compared to intravenous morphine. Trevena believes that oliceridine may offer an improved safety and tolerability profile compared to conventional opioid analgesics while providing powerful pain relief to patients. Trevena anticipates that the initial market opportunity for oliceridine will be in the

acute care settings, with a focus on moderate to severe acute pain in the hospital.

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 – oliceridine (TRV130) to manage moderate to severe acute pain intravenously (Phase 3), TRV027 to treat acute heart failure (Phase 2b), TRV734 to manage 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, including 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, including the Phase 2 oliceridine studies, will be indicative of the results of future trials; expectations for regulatory approvals and the positive impact, if any, of the FDA's grant of Breakthrough Therapy Designation status for oliceridine; 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.

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