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Trevena Announces FDA Grant of Fast Track Designation to Oliceridine (TRV130) 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 United States Food and Drug Administration (FDA) has granted Fast Track designation to oliceridine (TRV130) for the management of moderate-to-severe acute pain. Oliceridine is being developed as a potential replacement for currently approved intravenous opioid analgesics. In a recently completed Phase 2 study in postoperative pain, oliceridine matched the analgesic efficacy of morphine with an improved safety and tolerability profile. Trevena expects to initiate Phase 3 development of oliceridine in the first quarter of 2016.

“We believe that this Fast Track designation represents recognition by FDA of the significant unmet needs in the management of acute pain and of the potential for oliceridine to improve on current standards of care,” stated Maxine Gowen, Ph.D., chief executive officer. “We look forward to working closely with the FDA to rapidly advance the development of oliceridine.”

The Fast Track program, established under the FDA Modernization Act of 1997, is designed to facilitate the development and review of drugs intended to treat serious conditions with unmet medical needs by providing sponsors with the opportunity for frequent interactions with the FDA.

About moderate-to-severe acute pain

Mu opioid receptor agonists such as morphine and fentanyl are the most effective class of analgesics currently available and are the standard of care in moderate to severe acute pain; however, in published national surveys, a significant proportion of surgical patients have reported inadequate pain relief despite use of opioid analgesics. Opioid-related adverse effects such as respiratory depression, nausea and vomiting, are frequently dose-limiting, which complicates pain management and increases the burden of care.

About oliceridine

Oliceridine (TRV130) was designed to optimize opioid receptor pharmacology to deliver an improved analgesic profile. Oliceridine is a biased mu-opioid receptor ligand that in preclinical studies activated analgesic signals while avoiding signals that can interfere with analgesia and promote respiratory depression and gastrointestinal dysfunction. In August 2015, Trevena reported data from a Phase 2b trial comparing oliceridine to placebo and morphine following abdominoplasty surgery using on-demand patient-controlled analgesia.

In that trial, oliceridine demonstrated comparable efficacy to a standard regimen of morphine, with a significantly lower incidence of nausea, vomiting, and hypoventilation – a measure of respiratory safety. In previous clinical trials, oliceridine delivered profound levels of pain relief safely and rapidly compared to IV morphine, and doses of oliceridine that were more effective than morphine simultaneously depressed respiratory drive to a lesser degree than morphine. Trevena believes that oliceridine may offer an improved safety and tolerability profile compared to currently used 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 is developing four biased ligand product candidates it has identified – TRV027 to treat acute heart failure (Phase 2b), oliceridine (TRV130) to treat moderate to severe acute pain intravenously (completed Phase 2), 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; 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, including the impact, if any, of the Fast Track designation of oliceridine or the FDA's views on the unmet needs in the management of acute pain or the potential of oliceridine to improve on the current standards of care; 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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