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Trevena Announces Publication of Results from Phase 3 “Real World” Safety Study for Oliceridine in The Journal of Pain Research

Safety and tolerability demonstrated in diverse patient populations and surgeries

CHESTERBROOK, Pa., Nov. 20, 2019 (GLOBE NEWSWIRE) -- Trevena, Inc. (Nasdaq: TRVN), a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with central nervous system (CNS) disorders, today announced publication of results from the Phase 3 open-label safety study (ATHENA) for IV oliceridine in *The Journal of Pain Research*. The results highlight the safety and tolerability of oliceridine in the management of moderate-to-severe acute pain in a variety of surgical / medical settings and patient populations.

The publication, “ATHENA: A Phase 3, Open Label Study of the Safety and Effectiveness of Oliceridine (TRV130), a G-Protein Selective Agonist at the μ-Opioid Receptor, in Patients with Moderate to Severe Acute Pain Requiring Parenteral Opioid Therapy” with investigator and lead author, Sergio Bergese, M.D., Department of Anesthesiology, School of Medicine, Stony Brook University, is available online on Dove Medical Press.

“The results of this study show that oliceridine was generally safe and well-tolerated in a variety of surgical and medical conditions with acute pain. Additionally, oliceridine performed consistently in the patient population studied, including elderly and obese patients, who are at greater risk for developing opioid-related adverse effects,” said Dr. Bergese. “These findings suggest that oliceridine may represent a potential new treatment option for the management of moderate-to-severe acute pain where IV opioid therapy is warranted.”

Study Summary and Key Findings:

- This was a Phase 3, multi-center, open-label study that evaluated the safety of oliceridine in 768 patients with moderate-to-severe acute pain. It was conducted in 41 sites in the United States, including ambulatory surgical centers, hospital-based outpatient and inpatient settings, and emergency departments.

- In order to study oliceridine in a broad, “real world” context where IV analgesics are typically used, the protocol was designed with broader patient eligibility criteria, concomitant treatment allowances, and mode of administration (both clinician-directed bolus and patient-controlled analgesia were permitted as clinically indicated).

- The average age of patients in this study was 54 years. 32% of patients were 65 years or older, and 46% were considered obese with a body mass index (BMI) of 30 kg/m^2 or

higher. The study included patients with a range of co-morbidities, including diabetes, chronic / cancer pain and obstructive sleep apnea.

- Patients with post-surgical acute pain comprised the majority of the study population (94%). The most common procedure types were orthopedic (30%), colorectal (15%) and gynecological (15%).

- AEs were mostly of mild or moderate severity, and only 2% of patients discontinued treatment due to an AE. The most commonly reported adverse events (AEs) were nausea, vomiting, and constipation.

About Oliceridine

Oliceridine is a G protein biased (selective) mu-opioid receptor ligand in development for the management of moderate to severe acute pain in hospitals or other controlled clinical settings where intravenous 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 expects that oliceridine will be classified as a Schedule II controlled substance.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with CNS disorders. The Company has four novel and differentiated investigational drug candidates, including IV oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the acute treatment of migraine, and TRV734 for maintenance treatment of opioid use disorder. The Company has also identified TRV045, a novel S1P receptor modulator that may offer a new, non-opioid 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; 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, including whether IV opioids remain a necessary medication for many hospital patients and whether oliceridine might become a new option or clinically important alternative to help

hospitals and healthcare providers better manage their patients' pain; 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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