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# Trevena Announces Publication of Results from Special Population Studies for Oliceridine

**No dose adjustments required for patients with renal impairment or patients with mild / moderate hepatic impairment**

**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 two Phase 1 pharmacokinetic (PK) studies of IV oliceridine, one in patients with end-stage renal disease and one in patients with hepatic impairment, in *Clinical Pharmacology in Drug Development*. The results demonstrate that no dose adjustments are needed in patients with renal impairment or in patients with mild / moderate hepatic impairment.

The publication, “The Influence of Renal or Hepatic Impairment on the Pharmacokinetics, Safety, and Tolerability of Oliceridine” with lead author Anne Nafziger, M.D., Department of Medicine at St. Peter’s Hospital, Albany, NY, is available online at https://accp1.onlinelibrary.wiley.com/doi/10.1002/cpdd.750.

“Due to the accumulation of active metabolites, conventional IV opioids often require dosage adjustments when administered to patients with renal or hepatic impairment. The results of these two studies demonstrate that there is no clinically relevant difference in oliceridine clearance in patients with renal or hepatic dysfunction,” said Mark A. Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena, Inc. “These findings suggest that oliceridine may provide a new IV analgesic treatment option with clinical advantages for these at-risk patient populations.”

**Study Summary and Key Findings:**

- A Phase 1, multi-center, open-label study evaluated oliceridine PK, safety, and tolerability in 17 subjects with end-stage kidney disease. In these subjects with severe renal impairment, there was no clinically relevant change in oliceridine total clearance (>50% difference) or other PK parameters compared with healthy age- and sex-matched controls.
- A Phase 1, multi-center, open-label study evaluated oliceridine PK, safety, and tolerability in 34 subjects with mild, moderate, and severe hepatic impairment. In subjects with mild, moderate, and severe hepatic impairment, there were no clinically relevant differences in oliceridine total clearance compared with healthy subjects. Additional PK findings suggest that initial dose reduction in individuals with severe hepatic impairment should be considered, as they may require fewer doses of oliceridine compared to healthy individuals.

- The most commonly reported adverse events (AEs) were nausea, fatigue, and euphoria. All treatment-emergent AEs in both studies were of mild intensity.

**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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