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Trevena Announces Publication Highlighting Risk / Benefit Analysis of OLINVYK® in Pain and Therapy

Exploratory analysis shows OLINVYK treated patients are ~50% less likely to experience an AE compared to morphine patients at equivalent levels of analgesia

CHESTERBROOK, Pa., Aug. 10, 2021 (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 the publication of an exploratory analysis evaluating the safety of OLINVYK (oliceridine) injection and IV morphine, using data from the OLINVYK Phase 3 program. The findings suggest that under equianalgesic conditions, patients receiving OLINVYK were less likely to experience adverse events (AEs) compared to patients treated with morphine.

The publication is titled, “Oliceridine Exhibits Improved Tolerability Compared to Morphine at Equianalgesic Conditions: Exploratory Analysis from Two Phase 3 Randomized Placebo and Active Controlled Trials,” with lead author Gregory B. Hammer, M.D., Professor of Anesthesiology, Perioperative and Pain Medicine, and of Pediatrics at Stanford University (DOI: https://doi.org/10.1007/s40122-021-00299-0).

“IV opioids continue to play a key role in post-operative pain management in my practice. As clinicians, we are always focused on achieving the optimal balance of analgesia with minimal risks to our patients,” said Dr. Hammer. “These findings provide useful insight into the benefit-risk profile of OLINVYK and suggest that it can provide morphine-level pain relief with a lower risk of adverse events.”

Publication Key Points:

A logistic regression analysis of data from the two OLINVYK Phase 3 pivotal trials suggested that, at equal levels of analgesia comparing OLINVYK to IV morphine:

- OLINVYK-treated patients were ~50% less likely than morphine-treated patients to experience one or more treatment-emergent AEs of nausea, vomiting, sedation, dizziness, pruritus, or hypoxia.
- The odds ratio (OR) for a comparison of the effect of treatment with OLINVYK versus morphine was 0.507 for the pooled hard- and soft-tissue studies data ($p = 0.009$). An OR <1 indicates a lower likelihood of achieving the safety composite endpoint associated with OLINVYK treatment versus morphine. The OR was 0.499 ($p = 0.042$) and 0.542 ($p = 0.121$) for the hard-tissue and soft-tissue studies, respectively.

The publication can be found at https://www.trevena.com/publications.

“The findings from this analysis are compelling and suggest that OLINVYK may offer an improved benefit / risk profile for patients requiring IV opioids,” said Mark A. Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena. “Because all opioids carry risks, when prescribing OLINVYK, physicians should monitor their patients closely and refer to the Important Safety Information.”

About OLINVYK® (oliceridine) injection

OLINVYK is a new chemical entity approved by the FDA in August 2020. OLINVYK contains oliceridine, a Schedule II controlled substance with a high potential for abuse similar to other opioids. It is indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. OLINVYK is available in 1 mg/1 mL and 2 mg/2 mL single-dose vials, and a 30 mg/30 mL single-patient-use vial for patient-controlled analgesia (PCA). Approved PCA doses are 0.35 mg and 0.5 mg and doses greater than 3 mg should not be administered. The cumulative daily dose should not exceed 27 mg. Please see Important Safety Information, including the BOXED WARNING, and full prescribing information at www.OLINVYK.com.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative medicines for patients with CNS disorders. The Company has one approved product in the United States, OLINVYK® (oliceridine) injection, indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. The Company’s novel pipeline is based on Nobel Prize winning research and includes four differentiated investigational drug candidates: TRV250 for the acute treatment of migraine, TRV734 for maintenance treatment of opioid use disorder, TRV045 for diabetic neuropathic pain and epilepsy, and TRV027 for acute respiratory distress syndrome and abnormal blood clotting in COVID-19 patients.

For more information, please visit www.Trevena.com

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 and trials of its therapeutic candidates, plans for potential future product candidates, commercialization of approved drug products and other statements containing the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “objective,” “predict,” “project,” “suggest,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” “ongoing,” or the negative of these terms or 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 commercialization of any approved drug product, the status, timing, costs, results and interpretation of the Company’s clinical trials or any future trials of any of the Company’s investigational drug candidates; the uncertainties inherent in conducting clinical trials;

expectations for regulatory interactions, submissions and approvals, including the Company's assessment of the discussions with the FDA or other regulatory agencies about any and all of its programs; uncertainties related to the commercialization of OLINVYK; available funding; uncertainties related to the Company's intellectual property; uncertainties related to the ongoing COVID-19 pandemic, 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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