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Trevena Announces Two OLINVYK® Presentations at ANESTHESIOLOGY® 2021

Posters highlight safety and tolerability data in two complex patient populations at higher risk for adverse events

CHESTERBROOK, Pa., Oct. 13, 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 two presentations at ANESTHESIOLOGY® 2021, the national conference for the American Society of Anesthesiologists (ASA). Both posters highlighted safety data from the OLINVYK (oliceridine) injection program. The meeting was held on October 8th to 12th in San Diego, California.

“I am pleased that we continue to expand the published database underlying OLINVYK’s compelling product profile,” said Mark A. Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena. “The robust data that we have generated in clinically complex patients will continue to serve as valuable information for healthcare providers as they consider the use of OLINVYK in their post-operative patients.”

Poster details:

- E-Poster #1: “Elevated Body Mass Index Does Not Affect Adverse Events Associated With Oliceridine, An Intravenous Opioid Agonist” with lead author Joseph F. Answine, M.D., Assistant Professor of Anesthesiology, Penn State Health Milton S. Hershey Medical Center.

  This poster reports the incidence of opioid-related adverse events (ORAEs), stratified by BMI categories (<30 kg/m^2, 30-40 kg/m^2 and >40 kg/m^2), from the OLINVYK Phase 3 real world open-label safety study. In the post-operative setting, obesity is a known risk factor for developing ORAEs.

  - Obese patients (BMI > 30 kg/m^2) were not at an increased risk for developing ORAEs, despite having a higher incidence of medical comorbidities compared to non-obese patients.
  - In the study, 46% (352/768) of patients were obese, and 10% of patients were morbidly obese (BMI > 40 kg/m^2).
  - Selected by ASA’s Committee on Scientific Advisory for inclusion in a special in-person poster session on October 9th.

- E-Poster #2: “Safety Of Intravenous Oliceridine In Patients With Renal Impairment: Findings From A Phase 3 Open-label Study” with lead author Ashraf S. Habib, M.D., Professor of Anesthesiology, Duke University School of Medicine.

  This poster reports the incidence of ORAEs and opioid-induced respiratory depression (OIRD), defined by oxygen saturation (SpO_2) < 90% or respiratory rate (RR) < 10 bpm, in patients with renal impairment from the OLINVYK Phase 3 real world open-label safety study. In the post-operative setting, patients with renal impairment are at a high risk of developing serious ORAEs, and dosage adjustment is often required when administering IV opioids.

  - Patients with moderate to severe renal insufficiency, defined as stage 3 or higher chronic kidney disease (CKD), were not at an increased risk for developing ORAEs or OIRD, compared to patients with stage 1-2 CKD.
  - Among all study patients, none experienced SpO_2 < 90% and RR < 10 bpm at the same time, and no patients received naloxone during treatment with OLINVYK.
  - In the study, nearly 18% (137/768) of patients had stage 3 or higher CKD.

All posters can be found at https://www.trevena.com/publications.

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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