May 12, 2021

Trevena Announces Presentation of OLINVYK® Respiratory Safety Data in High-Risk Patients at the 46th Annual ASRA Meeting

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Elderly and obese patients receiving OLINVYK are not at increased risk for respiratory depression, compared to younger and non-obese patients, based on exploratory analysis

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CHESTERBROOK, Pa., May 12, 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 a poster presentation at the 46th Annual Regional Anesthesiology and Acute Pain Medicine (ASRA) Meeting. The conference is taking place on May 13th to 15th, 2021.

The poster highlights an exploratory analysis of respiratory safety data from the OLINVYK Phase 3 multi-site, open-label, "real world" study. The incidence of opioid-induced respiratory depression (OIRD) was similar between "high-risk" patients, defined as elderly **and** obese, and "low-risk" patients, defined as younger and non-obese. This lack of difference was observed despite the high-risk group having a higher average age, average BMI, comorbid burden, mean cumulative dose, and mean duration of exposure to OLINVYK. Advanced age and obesity are two well-recognized risk factors for developing OIRD.

"Complex patients with medical comorbidities pose unique challenges in postoperative pain management, due to their increased risk for developing adverse events such as respiratory depression," said Mark A. Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena, Inc. "The findings from this analysis are important and suggest that OLINVYK may be a clinically appropriate treatment option for these challenging patients. Physicians still need to be mindful that life-threatening respiratory depression from opioids is more likely to occur in elderly patients. Physicians should monitor them closely, particularly when initiating and titrating OLINVYK and when OLINVYK is given concomitantly with other drugs that depress respiration."

Poster Details

"Low Incidence of Opioid-Induced Respiratory Depression Observed with Oliceridine In High-Risk Elderly Obese Patients" (Poster #979, 5:30-6:00 p.m. ET, May 13th, 2021)

- High-risk patients (n=120) demonstrated a relatively low OIRD incidence of 10.8%,

which was numerically lower than the OIRD incidence of 14.6% in low-risk patients (n=268) and 12.9% in all patients.

- Out of 768 patients in the study, 33% were ≥ 65 years of age and 46% had a BMI of ≥ 30 kg/m^2. The average age in the high-risk group was 70 vs. 45 years in the low-risk group. The average BMI in the high-risk group was 35.6 kg/m^2 vs. 25.1 kg/m^2 in the low-risk group.

- The mean cumulative dose of OLINVYK was 37.1 mg in the high-risk group vs. 30 mg in the low-risk group. The mean duration of exposure was 39.8 hours in the high-risk group vs. 28.1 hours in the low-risk group.

- There was a higher incidence of other medical comorbidities in the high-risk group, including asthma, sleep apnea, chronic obstructive pulmonary disease, diabetes, and hypertension, which are also known to increase the risk of OIRD.

- OIRD was defined by administration of naloxone, a respiratory rate <10 bpm, or oxygen saturation < 90%. No naloxone administration was required for any patient treated with OLINVYK in the study.

The poster 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 epilepsy and chronic neuropathic pain, 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.

For more information, please contact:

Investor Contact:

Dan Ferry
Managing Director
LifeSci Advisors, LLC
daniel@lifesciadvisors.com
(617) 430-7576

PR & Media Contact:

Sasha Bennett
Director
Clyde Group
Sasha.Bennett@clydegroup.com
(239) 248-3409

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