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Trevena, Inc. Announces Publication Highlighting OLINVYK™ Respiratory Safety Data in High-Risk Patients in Pain & Therapy

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Low incidence of respiratory depression observed with OLINVYK (oliceridine) injection regardless of age or body mass index, in exploratory analysis

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CHESTERBROOK, Pa., Jan. 28, 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 a new analysis of respiratory safety data from the OLINVYK Phase 3 multi-site "real world" safety study in *Pain and Therapy*.

The publication is titled, "Low Incidence of Opioid-Induced Respiratory Depression Observed with Oliceridine Regardless of Age or Body Mass Index: Exploratory Analysis from a Phase 3 Open-Label Trial in Postsurgical Pain," with lead author Marek Brzezinski, M.D., Ph.D., Professor of Clinical Anesthesia, University of California San Francisco (DOI: https://doi.org/10.1007/s40122-020-00232-x).

Respiratory depression is a known risk of treatment with any opioid. The results of this analysis highlight no statistically significant difference in the incidence of opioid-induced respiratory depression (OIRD) between elderly and younger patients, or between obese and non-obese patients, all of whom received OLINVYK. Advanced age and obesity are two well-recognized risk factors for developing OIRD.

"Pain management with IV opioids remains a key strategy for optimal analgesic management in the postoperative setting. However, dose-limiting adverse effects, including respiratory depression, represent a major limitation to their safe and effective use – particularly in high-risk patients with medical comorbidities," said Dr. Brzezinski. "These findings are important and will serve as useful information for clinicians as they consider treatment options for their challenging patients.

Publication Key Points:

- Elderly patients (≥ 65 years) demonstrated no statistically significant difference in OIRD incidence compared to younger patients (10.8% vs. 15.1%, p=0.11).
- Obese patients (BMI ≥ 30) demonstrated no statistically significant difference in OIRD

incidence compared to non-obese patients (14.0% vs. 13.4%, p=0.80).

- Patients that were both elderly and obese (n=120) demonstrated a relatively low OIRD incidence of 10.8%, which was numerically lower than the overall OIRD incidence of 13.7% in all patients.

- Out of 724 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 elderly group was 71 vs. 46 years in the younger age group. The average BMI in the obese group was 36.7 kg/m^2 vs. 25.3 kg/m^2 in the non-obese group.

- 52% of all patients received OLINVYK by bolus dosing and 48% by patient-controlled analgesia (PCA). The median cumulative dose of OLINVYK was 21 mg with a median duration of exposure of 21.4 hours.

- Overall, 13.7% of all patients experienced OIRD defined by a respiratory rate <10 bpm or oxygen saturation < 90%, with none requiring naloxone for reversal of OIRD.

- The most commonly occurring medical comorbidities in the elderly and obese patient groups included sleep apnea, diabetes, and hypertension, which are also known to increase the risk of OIRD.

“With this publication, we continue to add to the robust collection of peer-reviewed literature for OLINVYK that is available to clinicians,” said Mark Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena, Inc. “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.”

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 novel 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 also has four novel and differentiated investigational drug candidates: TRV250 for the acute treatment of migraine, TRV734 for maintenance treatment of opioid use disorder, and TRV027 for acute

lung injury / abnormal blood clotting in COVID-19 patients. The Company has also identified TRV045, a novel S1P receptor modulator that may offer a new, non-opioid approach to treating a variety of CNS disorders.

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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