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Trevena, Inc. Announces Publication Highlighting GI Tolerability Profile of OLINVYK™ (oliceridine) injection in Pain and Therapy

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OLINVYK significantly reduced risk of vomiting and rescue antiemetic use compared to IV morphine in a retrospective analysis

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CHESTERBROOK, Pa., Nov. 20, 2020 (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 publication, titled "Oliceridine is Associated with Reduced Risk of Vomiting and Need for Rescue Antiemetics Compared to Morphine: Exploratory Analysis from Two Phase 3 Randomized Placebo and Active Controlled Trials," with lead author Tim Beard, M.D., Chair of the Department of Surgery at Summit Medical Group (DOI: https://doi.org/10.1007/s40122-020-00216-x).

The results of this analysis highlight an improved gastrointestinal (GI) tolerability profile, with OLINVYK demonstrating a ~2-3x likelihood of achieving a "complete GI response" compared to IV morphine under equianalgesic conditions. A complete GI response is defined as the proportion of patients who complete the study without vomiting and without using any antiemetics.

"There are multiple types of procedures where post-operative nausea or vomiting can disrupt the integrity of a surgery, posing a significant challenge to a patient's recovery," said Tim Beard, M.D. "Based on the results of this analysis, OLINVYK has the potential to greatly reduce the risk of nausea and vomiting following surgery, compared to IV morphine. These are compelling findings that suggest the clinical advantages OLINVYK may offer in the post-operative acute care setting."

Publication Key Points:

- ***Orthopedic surgery-bunionectomy study:*** A higher proportion of patients achieved 'complete GI response' with all OLINVYK treatment regimens (0.1 mg: 76.3%; 0.35 mg: 53.2%; 0.5 mg: 49.4%) compared to IV morphine (32.9%; $p < 0.05$ for all 3 OLINVYK dose regimens).

- ***Plastic surgery-abdominoplasty study:*** A higher proportion of patients achieved 'complete GI response' with all OLINVYK treatment regimens (0.1 mg: 59.7%; 0.35 mg:

39.2%; 0.5 mg: 29.9%) compared to IV morphine (28.8%; p ≤ 0.0001 for OLINVYK 0.1 mg).

- ***Pooled data from both trials:*** There was a statistically significantly higher rate of 'complete GI response' associated with OLINVYK 0.1 mg (68%) and 0.35 mg (46.2%) compared to IV morphine (30.8%; p ≤ 0.005).

- ***Under equianalgesic conditions***: Where analgesia as measured by Sum of Pain Intensity Difference (SPID) scores was held constant, patients were 3.1x more likely to achieve a 'complete GI response' with OLINVYK than IV morphine in the orthopedic surgery-bunionectomy study (95% CI: 1.78, 5.56; p <0.0001), and 1.9x more likely in the plastic-surgery abdominoplasty study (95% CI: 1.09, 3.36; p = 0.024).

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 single bolus doses greater than 3 mg have not been evaluated. 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.

For more information, please contact:

Investor Contact:

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

Company Contact:

Bob Yoder
SVP and Chief Business Officer
Trevena, Inc.
(610) 354-8840

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