August 26, 2020

Trevena Announces Publications of OLINVYK™ Respiratory Safety Analyses vs. IV Morphine

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Publication in Anesthesiology: Favorable benefit-risk profile for OLINVYK (oliceridine) injection as measured by clinical utility function analysis

Publication in Clinical Drug Investigation: Lower incidence of respiratory depression associated with OLINVYK as measured by frequency / duration of dosing interruption

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CHESTERBROOK, Pa., Aug. 26, 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 two publications of the respiratory safety data from the OLINVYK development program. Both publications highlight data showing an improved respiratory safety profile for OLINVYK compared to IV morphine.

“These two publications add to the comprehensive safety database of peer-reviewed published literature for OLINVYK,” said Mark Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena, Inc. “We believe these data will provide important information to clinicians and other healthcare decision-makers in managing acute pain patients in the hospital setting.”

1.) Benefit and Risk Evaluation of Biased μ-Receptor Agonist Oliceridine versus Morphine, by lead author Albert Dahan, M.D., Ph.D., Professor of Anesthesiology, Leiden University Medical Center.
(https://doi.org/10.1097/ALN.0000000000003441)

Study Summary and Key Findings:

- A clinical utility function analysis was conducted on the ventilatory response to hypercapnia (VRH) data from the OLINVYK Phase 1 study. VRH is a validated measure of respiratory function, and opioid medications are known to interfere with the body’s normal respiratory drive in response to elevated CO_2 levels (hypercapnia). Clinical utility function analysis integrates the relative probability of analgesia and respiratory depression over the therapeutic plasma concentration range of a medication.

- OLINVYK was associated with a higher probability of analgesia than respiratory

depression, while the reverse was true for morphine.

- The clinical utility function model predicted there would be a lower probability of a respiratory event occurring with OLINVYK versus morphine.

- Over the clinically relevant concentration range, OLINVYK had a higher probability of providing analgesia than producing respiratory depression, while morphine had a higher probability of producing respiratory depression than providing analgesia.

2.) Evaluating the Incidence of Opioid-Induced Respiratory Depression Associated with Oliceridine and Morphine as Measured by the Frequency and Average Cumulative Duration of Dosing Interruption in Patients Treated for Acute Postoperative Pain, by lead author Sabry Ayad, M.D., Department of Anesthesiology at Cleveland Clinic.
(https://link.springer.com/article/10.1007%2Fs40261-020-00936-0)

Study Summary and Key Findings:

- In a secondary analysis of two Phase 3 randomized controlled trials using PCA dosing in orthopedic and plastic surgeries, the rate of dosing interruptions due to a respiratory safety event and average cumulative duration of interruptions was reported for both OLINVYK and IV morphine.

- In both studies, the proportion of patients with dosing interruptions was higher with morphine 1 mg (17.1% in orthopedic surgery and 25.6% in plastic surgery) compared to OLINVYK 0.35 mg (7.6% in orthopedic surgery, 20.3% in plastic surgery) and 0.5 mg (11.4% in orthopedic surgery, 18.8% in plastic surgery).

- A higher proportion of patients with dosing interruptions was also observed with morphine compared to OLINVYK when the two studies were pooled (morphine 1 mg: 21.5%, OLINVYK 0.35 mg: 13.9%, OLINVYK 0.5 mg: 15.1%).

- The average cumulative duration of interruptions was also lower for all OLINVYK demand doses in both Phase 3 studies compared to morphine.

- Using dosing interruptions as a potential surrogate for opioid-induced respiratory depression suggests improved respiratory safety with OLINVYK versus morphine.

About OLINVYK™ (oliceridine) injection

OLINVYK is a new chemical entity approved by the FDA in August 2020. 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 will not be available for distribution until the United States Drug Enforcement Administration assigns it to its schedule of controlled substances. 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 U.S., 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.

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

Source: Trevena Inc.