October 5, 2020

Trevena, Inc. Announces Three OLINVYK™ Presentations at the Virtual American Society of Anesthesiologists 2020 Annual Meeting

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Posters highlight improvements in respiratory safety and gastrointestinal tolerability associated with OLINVYK (oliceridine) injection vs. IV morphine

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CHESTERBROOK, Pa., Oct. 05, 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 three presentations at ANESTHESIOLOGY® 2020, the national conference for the American Society of Anesthesiologists (ASA). The conference was held virtually from October 2nd to 7th, 2020. The presentations included three posters, all of which discussed new analyses of data from the OLINVYK Phase 3 program.

“Throughout its clinical development, OLINVYK has demonstrated a consistently favorable side effect profile,” said Mark Demitrack, M.D., Senior Vice President and Chief Medical Officer of Trevena, Inc. “I am pleased that we are still gaining valuable clinical insights into its differentiated profile as we continue to examine the robust Phase 3 data, which is clearly of great interest to clinicians looking for alternative treatment options for the treatment of acute pain.”

Poster Details

1. (Poster #A4280) “Evaluating Predictive Value Of Postoperative O_2 Saturation Levels To Rate Of Respiratory Safety Events In Oliceridine Trials,” with lead author Sabry Ayad, M.D., Department of Anesthesiology at Cleveland Clinic.

- OLINVYK demonstrated an overall lower incidence of respiratory safety events (RSEs) (12.8% - 13.8%) compared with IV morphine (22.8% - 23.4%) in Phase 3 randomized controlled trials (RCTS) in orthopedic and plastic surgeries.
- In these OLINVYK Phase 3 RCTs, respiratory safety was assessed using a predefined RSE measure. An analysis was conducted to determine the correlation between RSEs and oxygen saturation (SpO_2) < 90%, a known independent risk factor of early postoperative respiratory complications and resource utilization.

- The analysis showed that SpO_2 < 90% was predictive of an RSE and may serve as a valuable objective measure within a health economic model for OLINVYK.

2. (Poster #A4281) “Improved Tolerability With Oliceridine Compared To Morphine At Equianalgesic Doses,” with lead author Gregory Hammer, M.D., Professor of Anesthesiology, Perioperative and Pain Medicine, and of Pediatrics at Stanford University.

A secondary analysis was conducted on the data from the OLINVYK Phase 3 pivotal RCTs in order to evaluate the safety of OLINVYK, compared to IV morphine, when adjusted for equal levels of analgesia. A composite safety endpoint was defined using the adverse events (AEs) that occurred in ≥ 10% of patients who received either OLINVYK or IV morphine (nausea, vomiting, sedation, dizziness, pruritus, and hypoxia). The incidence of the individual AEs was also assessed.

- Following orthopedic surgery, OLINVYK demonstrated a significantly lower odds ratio ($p < 0.05$) for rates of nausea, vomiting, and pruritus, compared to IV morphine.

- Following plastic surgery, OLINVYK demonstrated a significantly lower odds ratio ($p < 0.05$) for rates of nausea, vomiting, and sedation compared to IV morphine.

- At equianalgesic levels, OLINVYK’s odds ratio for the composite safety endpoint was approximately half of that associated with IV morphine. The findings were consistent across both studies.

3. (Poster #A4284) “Reduced Incidence Of Postoperative Vomiting With Oliceridine Than Morphine At Equianalgesic Doses,” with lead author Tim Beard, M.D., Chair of the Department of Surgery at Summit Medical Group.

A retrospective analysis was conducted on the gastrointestinal (GI) tolerability data from the OLINVYK Phase 3 RCTs, using a ‘complete GI response’ endpoint. A ‘complete GI response’ is defined as the proportion of patients who complete the study without vomiting and without using any anti-emetics.

- In both studies, OLINVYK 0.1 mg and 0.35 mg were associated with a significantly higher rate of ‘complete GI response’ compared with IV morphine.

- Under equianalgesic conditions, where analgesia as measured by Sum of Pain Intensity Difference (SPID) scores was held constant, the odds ratio for ‘complete GI response’ was higher with OLINVYK than IV morphine.

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. 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 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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