November 2, 2017

Trevena Announces Submission of New Drug Application to U.S. FDA for OLINVO™ (oliceridine injection)

– Filing supported by positive Phase 3 APOLLO and ATHENA studies –

CHESTERBROOK, Pa., Nov. 02, 2017 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) today announced that it has recently submitted its New Drug Application (NDA) for OLINVO™ (oliceridine injection) to the U.S. Food and Drug Administration (FDA). OLINVO is the first G protein biased ligand of the mu opioid receptor, a new class of opioid receptor modulator, and the first pain program to receive Breakthrough Therapy designation from the FDA.

The submission includes data showing that intravenous OLINVO demonstrated analgesic efficacy in all three dosing regimens tested in the two Phase 3 APOLLO pivotal efficacy studies. These trials were designed to support an indication for the management of moderate-to-severe acute pain in adult patients for whom an intravenous opioid is warranted.

The filing also includes safety and tolerability data for over 1,100 patients administered OLINVO across Phase 2 and Phase 3 studies, including the ATHENA open label safety study. Additional pharmacokinetic data, clinical pharmacology data, and results from five randomized controlled trials with head to head comparisons to morphine support potential differentiation of OLINVO.

“OLINVO was designed to fill a major gap in the set of medicines available for managing moderate to severe pain in the hospital,” said Maxine Gowen, Ph.D., chief executive officer. “Despite availability of non-opioid analgesics and advances in multimodal analgesia, tens of millions of patients still require IV opioids following surgery, during severe illness, or after trauma. Millions of these patients remain at risk for opioid-related adverse events, including respiratory depression or postoperative vomiting. We look forward to working with the FDA during the review process and to a potential NDA approval of OLINVO in 2018.”

About OLINVO™ (oliceridine injection)

OLINVO is a next generation IV analgesic for the management of moderate-to-severe acute pain in the hospital and similar settings and has been granted Breakthrough Therapy designation by the FDA. OLINVO was specifically designed to improve conventional opioid pharmacology to deliver the pain-reducing potential of an opioid but with fewer associated adverse effects via its biased ligand mechanism of action. In Phase 2 and Phase 3 clinical trials, OLINVO provided rapid and powerful analgesic efficacy while demonstrating a wider therapeutic window compared to morphine, suggesting it may be highly effective and well-tolerated for patients in need of strong analgesia. OLINVO is an investigational product and

has not been approved by the FDA or any other regulatory agency. The Company expects OLINVO to be a Schedule II controlled substance.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on providing better, safer therapies to patients in pain. The Company has leveraged breakthrough science to discover and develop its investigational product OLINVO for the management of moderate-to-severe acute pain. The Company has an early stage pipeline of new chemical entities targeting novel mechanisms of action, including for acute migraine, neuropathic pain, and other indications.

Cautionary note on 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 of its therapeutic candidates, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and 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 status, timing, costs, results and interpretation of the Company's clinical trials; the uncertainties inherent in conducting clinical trials; expectations for regulatory approvals, including with respect to the OLINVO NDA; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; uncertainties related to the Company's intellectual property; 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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