

# Trevena Announces Publication and Presentations of OLINVO™ (oliceridine injection) Clinical Data

 American Society of Anesthesiologists Annual Meeting presentations highlight OLINVO data from positive Phase 3 trials –

OLINVO Phase 2b data published in Journal of Pain Research

CHESTERBROOK, Pa., Oct. 25, 2017 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) today announced that it presented two posters describing the results of APOLLO-1 and APOLLO-2, the Company's two successful Phase 3 pivotal efficacy studies of OLINVO, at the 2017 Annual Meeting of the American Society of Anesthesiologists (ASA) held in Boston from October 21-25, 2017. The Company also announced that results of its Phase 2b trial of Breakthrough Therapy-designated OLINVO (oliceridine injection) have been published in the peer-reviewed Journal of Pain Research.

"I'm pleased to see continued peer-reviewed publication and presentation of our head to head comparisons of OLINVO to IV morphine," said Maxine Gowen, Ph.D., chief executive officer. "We know physicians and hospitals want to understand how a new therapy compares to current options. All too often new medications are launched without this data. With growing recognition that the burden of opioid-related adverse effects remains high, but that IV opioids remain necessary medications for many hospital patients, we look forward to submitting our NDA this month in the expectation that OLINVO will become a new option to help hospitals and healthcare providers better manage their patients' pain."

# Presentations at American Society of Anesthesiologists (ASA)

At the ASA meeting, the Company presented data from both Phase 3 APOLLO studies. The data highlighted the significant and rapid efficacy of OLINVO in managing moderate-to-severe acute pain, and included head-to-head comparisons to IV morphine demonstrating improvement on multiple measures of respiratory safety and postoperative nausea and vomiting. These data suggest that OLINVO has the potential to be a valuable new analgesic option for patients at risk of opioid-related adverse events. Abstracts from the ASA presentations are available online:

http://www.abstractsonline.com/pp8/#!/4328/presentation/16988; http://www.abstractsonline.com/pp8/#!/4328/presentation/11614

In addition to these two presentations, the Company sponsored a disease awareness booth at the ASA meeting to help educate attendees on advances in opioid pharmacology, and potential impact on the clinical and economic consequences of opioid-induced respiratory depression and post-operative nausea and vomiting.

## **Publication of Phase 2b data**

Full results of the Company's Phase 2b trial have been published in the Journal of Pain Research. In this randomized, controlled, double-blind Phase 2b study, intravenous OLINVO demonstrated rapid and powerful analgesic efficacy with statistically significantly reduced frequency of opioid-related adverse events including nausea, vomiting, and respiratory safety events compared to intravenous morphine. This study was the basis for the two successful APOLLO Phase 3 pivotal efficacy studies of OLINVO. The full publication is available online: <a href="https://www.dovepress.com/getfile.php?fileID=38764">https://www.dovepress.com/getfile.php?fileID=38764</a>

## 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 U.S. Food and Drug Administration (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. 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, and the expected timing of the NDA submission for OLINVO; the uncertainties inherent in conducting clinical trials; expectations for regulatory approvals; 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, including whether IV opioids remain a necessary medication for many hospital patients and whether OLINVO might become a new option to

help hospitals and healthcare providers better manage their patients' pain; 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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