

# Trevena Announces Publication of APOLLO-1 Results in The Journal of Pain Research Highlighting Oliceridine's Potential for Management of Moderate-to-Severe Acute Pain

CHESTERBROOK, Pa., March 11, 2019 (GLOBE NEWSWIRE) -- **Trevena, Inc. (NASDAQ: TRVN)**, a biopharmaceutical company focused on the development and commercialization of innovative treatment options that target and treat diseases affecting the central nervous system, or CNS, today announced publication of APOLLO-1 (Phase 3) results in *The Journal of Pain Research* on the effects of oliceridine (TRV130) for management of moderate-to-severe acute pain following bunionectomy.

The publication, "APOLLO-1: A randomized placebo- and active-controlled phase III study investigating oliceridine (TRV130), a G protein–biased ligand at the  $\mu$ -opioid receptor, for management of moderate-to-severe acute pain following bunionectomy," with lead author, Eugene R Viscusi, M.D., Professor of Anesthesiology, Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, PA, is available online at <https://www.dovepress.com/journal-of-pain-research-archive41>.

"In this study, oliceridine was found to provide relief that was statistically superior to placebo in patients with moderate-to-severe acute post-surgical pain," said Dr. Viscusi. "The results of the APOLLO-1 Phase 3 study suggest that oliceridine has the potential to be a clinically important alternative to conventional IV opioids for moderate-to-severe acute pain."

## Study Summary and Key Findings:

- In APOLLO-1, a Phase 3 clinical study, 389 patients were administered either oliceridine (TRV130), morphine or placebo intravenously (IV) for 48 hours following bunionectomy.
- There were 3 dosing regimens for oliceridine (0.1mg, 0.35mg, and 0.5mg) and one for morphine (1mg), each self-administered by the patient as needed to control their pain.
- Findings showed that the onset of analgesia for oliceridine was rapid and the proportion of treatment responders in the two higher oliceridine dosing regimens was similar to patients receiving morphine.
- The most commonly reported adverse effects (AEs) were nausea, vomiting, headache, and dizziness. Fewer patients receiving oliceridine discontinued treatment due to an AE than patients receiving morphine.

- Efficacy, safety, and tolerability data provide important context for evaluating the benefit/risk profile of IV oliceridine compared to morphine, and suggest that oliceridine may provide an important treatment option for the management of patients experiencing moderate-to-severe acute pain.

### **About Oliceridine**

Oliceridine is a G protein biased (selective) mu-opioid receptor (MOR) ligand in development for the management of moderate to severe acute pain in hospitals or other controlled clinical settings where intravenous (IV) therapy is warranted. It is a new chemical entity with a novel mechanism of action that enables more selective targeting of newly discovered pathways with the potential for fewer side effects. Oliceridine is an investigational product and has not been approved by the FDA or any other regulatory agency. If approved, the Company has requested that oliceridine be classified as a Schedule II controlled substance.

### **About Trevena**

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative treatment options that target and treat diseases affecting the central nervous system, or CNS. The Company has three novel and differentiated investigational drug candidates, including IV oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the treatment of acute migraine, and TRV734 for pain and/or management of opioid dependence. In its preclinical programs, Trevena is evaluating a set of novel S1P receptor modulators that may offer a new, non-opioid approach to managing chronic pain.

### **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; 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 oliceridine might become a new option or clinically important alternative 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.

**For more information, please contact:**

**Investor Contact:**

Valter Pinto / Allison Soss

KCSA Strategic Communications

Phone: 212-896-1254 / 212-896-1267

Email: [IR@trevena.com](mailto:IR@trevena.com)

**Company Contact:**

Bob Yoder, SVP and Chief Business Officer

Trevena, Inc.

Phone: 610-354-8840



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