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Trevena Announces Publication of APOLLO-2 Results in Pain Practice

CHESTERBROOK, Pa., June 24, 2019 (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) conditions, today announced publication of APOLLO-2 (pivotal Phase 3) results in *Pain Practice* on the effects of oliceridine (TRV130) for management of moderate-to-severe acute pain following abdominoplasty.

The publication: “APOLLO-2: A Randomized, Placebo and Active-Controlled Phase III Study Investigating Oliceridine (TRV130), a G Protein-Biased Ligand at the μ-Opioid Receptor, for Management of Moderate to Severe Acute Pain Following Abdominoplasty”, with lead author, Neil Singla, M.D., CEO of Lotus Clinical Research, is available online at https://doi.org/10.1111/papr.12801.

“IV opioids remain an important option for physicians in managing post-surgical moderate to severe acute pain for a subset of patients. In this study, oliceridine provided statistically superior pain relief compared to placebo, with a rapid onset of action and a favorable safety profile,” said Dr. Singla. “These results are consistent with those seen in the APOLLO-1 pivotal Phase 3 study in bunionectomy patients, suggesting that oliceridine is efficacious and well-tolerated, and could provide pain relief for patients with moderate to severe acute pain.”

Study Summary and Key findings:

- In APOLLO-2, a Phase 3 randomized, double-blind, placebo- and active-controlled clinical study, 401 patients were administered either oliceridine, morphine, or placebo intravenously (IV) for 24 hours following abdominoplasty.

- There were three 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.

- The primary endpoint of the study was achieved: the proportion of treatment responders in all the oliceridine treatment regimens was statistically significantly superior to placebo.

- Findings showed that the onset of analgesia with 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 events (AEs) in the study were nausea, vomiting, somnolence, and headache.

- The proportion of patients experiencing a respiratory safety event was lower in all oliceridine treatment groups compared to morphine, though this difference did not reach statistical significance.

- The efficacy, safety and tolerability data from this study are consistent with those seen in prior published clinical studies of IV oliceridine and suggest that oliceridine may represent an important new therapeutic alternative for the treatment of patients with moderate-to-severe acute pain where an IV opioid is warranted.

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 expects that oliceridine will be classified as a Schedule II controlled substance.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with Central Nervous System (CNS) conditions. 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.

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