January 4, 2017

Trevena Completes Enrollment of Phase 3 APOLLO Pivotal Efficacy Trials of Oliceridine for Moderate-to-Severe Acute Pain

Top-line results expected later this quarter

KING OF PRUSSIA, Pa., Jan. 04, 2017 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) today announced that it has completed enrollment of its Phase 3 APOLLO-1 and APOLLO-2 pivotal efficacy studies of oliceridine (TRV130) in moderate-to-severe acute pain following bunionectomy and abdominoplasty, respectively.

“We are pleased to have completed enrollment in these important studies and to confirm that the APOLLO trials remain on schedule to report top-line results in the first quarter of 2017,” said Maxine Gowen, Ph.D., chief executive officer. “We look forward to sharing these data when they become available.”

The APOLLO studies were designed based on the Phase 2 clinical trials of oliceridine that were successful in showing potential differentiation of oliceridine from morphine. The Company expects top-line results to include measures of efficacy, safety, and tolerability of oliceridine compared to both placebo and morphine.

In addition, the Company announced that patient enrollment for the Phase 3 ATHENA multi-procedure safety study remains on track. The Company continues to anticipate filing a New Drug Application (NDA) for oliceridine with the U.S. Food & Drug Administration (FDA) in the second half of 2017.

About the APOLLO-1 and APOLLO-2 Studies

Both APOLLO trials are Phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of oliceridine for the treatment of moderate to severe acute pain. The APOLLO-1 study is evaluating pain for 48 hours following bunionectomy, and the APOLLO-2 study is evaluating pain for 24 hours following abdominoplasty. In each trial, patients were randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) device for the management of their post-operative pain. Each study enrolled approximately 375 patients, allocated equally across study arms. The primary objective in each study is to evaluate the analgesic efficacy of oliceridine compared to placebo. Secondary endpoints include comparisons of efficacy, safety, and tolerability of oliceridine to morphine.

About Oliceridine

Oliceridine, Trevena's lead product candidate, is a next generation IV analgesic in Phase 3 development for the management of moderate-to-severe acute pain and has been granted Breakthrough Therapy designation by the FDA. Oliceridine was specifically designed to improve conventional opioid pharmacology to deliver the pain-reducing potential of an opioid but with fewer associated adverse effects. In a Phase 2b clinical trial, oliceridine 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. Oliceridine is an investigational product and has not been approved by the FDA or any other regulatory agency.

About Trevena

Trevena, Inc. is a biopharmaceutical company developing innovative therapies based on breakthrough science to benefit patients and healthcare providers confronting serious medical conditions. The Company has discovered four novel and differentiated drug candidates, including oliceridine. Trevena also has discovered TRV250, in preclinical development for the treatment of migraine, as well as TRV734 for pain and TRV027 for acute heart failure. The Company maintains an early stage portfolio of drug discovery programs.

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, including the expected timing of the release of top-line data from the APOLLO studies and the expected timing of the NDA filing for oliceridine; the uncertainties inherent in conducting clinical trials, including whether the Phase 3 studies will support regulatory approval of oliceridine and any potential differentiation of oliceridine from conventional opioids; whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials, such as the Phase 2 studies of oliceridine, will be indicative of the results of future trials; expectations for regulatory approvals, including for oliceridine; 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.

Contacts

Trevena, Inc.

Investors:
Jonathan Violin, Ph.D.
Sr. Director, Investor Relations
610-354-8840 x231
jviolin@trevena.com

or

Media:
Public Relations
PR@trevena.com

Source: Trevena Inc.