July 20, 2017

Trevena To Host 2017 Analyst Day and Announce Results of ATHENA Open Label Safety Study of OLINVO

– Company now plans to submit its New Drug Application for OLINVO™ (oliceridine injection) in September or October 2017 –

– Topline results from ATHENA safety study further support potential value of OLINVO in patients at risk of opioid-related adverse events –

– Pipeline progress includes continuing Phase 1 study of TRV250 for acute migraine and newly disclosed preclinical S1P modulator program –

KING OF PRUSSIA, Pa., July 20, 2017 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) today announced that it will host an Analyst Day in New York City beginning at 12:00 pm today with leading clinicians and Company management discussing the Company's portfolio of innovative investigational drugs, including new data and commercial strategy for its lead program, OLINVO™ (oliceridine injection), for moderate to severe acute pain. To join the live audio webcast of the presentation, please visit the Investor section of the Company's website. Following the conclusion of the presentation, the webcast will be available until August 20, 2017.

"We're pleased to share a number of important updates for OLINVO and our R&D pipeline," said Maxine Gowen, Ph.D., chief executive officer of Trevena. "Observations from the ATHENA open label study and new analysis of the burden of opioid-related adverse effects in hospitalized patients now complement the randomized controlled APOLLO studies to position OLINVO as a potentially valuable new option for patients who require IV opioids but are at risk of opioid related adverse effects. Our commercial strategy will target select procedures and specialties to focus on bringing OLINVO to these patients."

At the event, four leading external clinicians and researchers will discuss care practices, unmet needs, and OLINVO data:

- Eugene R. Viscusi, M.D., Professor of Anesthesiology at the Sidney Kimmel Medical College at Thomas Jefferson University, will discuss the landscape for acute pain management and present an overview of the randomized controlled trial data for OLINVO.

- Peter Whang, M.D., FACS, Associate Professor of Orthopaedics & Rehabilitation at Yale University School of Medicine, will discuss unmet needs in orthopedic surgery, including new analysis of a hospital administrative billing database detailing the prevalence and costs of opioid-related adverse events in hospitalized orthopedic patients.

- Michael H. Bourne, M.D., Chairman of Orthopaedic Surgery at St. Mark's Hospital and an investigator in the ATHENA study, will discuss how IV opioids are used in his practice, present topline results of the ATHENA study, and report observations of OLINVO performance in the patients treated at his site.

- Hadi Najafian, D.O., FACS, FASCRS, Chief of Colorectal Surgery at St. Joseph's Westgate Medical Center, will discuss the use of IV opioids in pain management following colorectal surgery and the potential impact of OLINVO on patient outcomes.

OLINVO program updates to be discussed

- New data from an analysis of an administrative billing database (the Premier Perspective® Hospital Database) quantify the substantial burden of illness associated with opioid-related adverse events (ORAEs) in 80 procedures across 8 medical specialties that will be basis for the Company's initial commercialization efforts. This analysis shows that patients having these procedures require substantial doses of IV opioids despite multimodal analgesia, and that the prevalence and costs associated with ORAEs are significant. Specifically:

  • Postoperative nausea and vomiting in patients receiving parenteral opioids occurs in 44-72% of patients and costs $1,600-$8,900 per event across specialties.

  • Postoperative respiratory compromise occurs in 3-17% of patients and costs $4,600-$20,000 per event across specialties.

- The Company has completed enrollment of patients in the ATHENA study to support its planned NDA submission. In the study, 772 patients were administered OLINVO to manage pain associated with a wide range of procedures and diagnoses. The most frequent procedures were orthopedic, gynecologic, colorectal, general, and plastic surgeries. Patients at risk of opioid-related adverse events were common, including patients over 65 years old and obese patients. OLINVO was administered by titration in post-anesthesia recovery rooms, as-needed by bolus injection, and by patient-controlled analgesia. Discontinuation rates were less than 5% for lack of efficacy or for adverse effects.

- Investigator-reported observations from the ATHENA study included a retrospective chart review in which colorectal surgery patients administered OLINVO at one site in the ATHENA study had return of bowel function 28 hours faster than similar patients at the same site treated with conventional opioids prior to the ATHENA study ($p=0.0001$ vs. historical control).

- The Company has successfully completed its chemical, manufacturing, and controls (CMC), nonclinical, and clinical Type-B pre-NDA meetings with the U.S. Food and Drug Administration (FDA), and now plans to submit the OLINVO NDA to the FDA in September or October of 2017.

- The Company is planning an open label investigation of OLINVO in key procedures that may yield additional investigator observations to inform potential prescribers and

identify potential future studies.

- The Company will outline its commercial strategy for OLINVO and discuss its initial focus on patients who are at greater risk of ORAEs. Specifically, the Company expects to target medical education and post-approval promotion to eight physician specialties with 80 select procedures and diagnoses where pain is most severe and/or prolonged, and procedure, comorbidity, or demographic factors place patients at elevated risk of opioid-related adverse effects. These patients comprise approximately 7 to 9 million annual hospital inpatients in the U.S.

Pipeline updates to be discussed

- TRV250, Trevena's selective delta receptor modulator for treatment of acute migraine, is currently under investigation in a single ascending dose trial in healthy volunteers. This study is evaluating the safety, tolerability, and pharmacokinetics of subcutaneous and oral TRV250, with results expected in the second half of 2017.

- The Company disclosed a new preclinical lead optimization program targeting S1P receptors with a novel mechanism that has demonstrated activity in preclinical models of chemotherapy-induced peripheral neuropathy, neuropathic pain, and inflammatory pain. Trevena's compounds are expected to be non-addictive and to avoid the immune suppression associated with approved and investigational S1P receptor targeted drugs.

Corporate update

Separately, the Company today announced that its chief medical officer, David Soergel, M.D., is planning to depart from the Company in late August to pursue a new opportunity. "While I am sad to see David leave, I am extremely grateful for the extraordinary dedication and thoughtfulness he has brought to Trevena for the last seven years," said Dr. Gowen. "I wish him the best of luck and am confident he will continue to excel in the future as he has at Trevena."

A search for a new chief medical officer is ongoing.

Conference call and webcast

Date: Thursday, July 20, 2017
Time: 12:00 p.m. EDT
Telephone Access: (855) 465-0180
International: (484) 756-4313
Conference ID: 53894172

To join the live audio webcast of the presentation, please visit theInvestor section of the Company's website. Following the conclusion of the presentation, the webcast will be available until August 20, 2017.

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's lead program is OLINVO™ (oliceridine injection), which has completed two successful Phase 3 trials for the management of moderate-to-severe acute pain. Trevena has discovered four novel and differentiated drug candidates, including OLINVO. Trevena also has discovered TRV250, in early clinical development for the treatment of acute migraine. 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 or any future trials, including the interpretation of the topline results from the APOLLO and ATHENA trials, whether the Company will undertake any additional open-label investigations of OLINVO, whether the existing clinical data is sufficient to support the Company's NDA to FDA, and whether OLINVO has the potential to positively impact patient outcomes; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals, including whether the pre-NDA meetings with FDA were successful and whether the Company will submit the OLINVO NDA in September or October of 2017; 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, including with respect to compounds for which the Company does not yet have patent protection; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates, including whether physicians, patients, and payers will conclude that OLINVO represents a potentially valuable new option for patients who require IV opioids but are at risk for ORAEs; 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.
Vice President, Corporate Strategy & Investor Relations

610-354-8840 x231
jviolin@trevena.com

or

Media:

Public Relations
PR@trevena.com

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