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Trevena Announces Presentations at the 42nd Annual Regional Anesthesiology and Acute Pain Medicine Meeting

Two posters highlight positive Phase 3 data comparing OLINVO™ (oliceridine injection) with intravenous morphine

KING OF PRUSSIA, Pa., April 06, 2017 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) today announced the first scientific presentation of positive results from two Phase 3 pivotal efficacy studies of OLINVO™ (oliceridine injection), an investigational, next-generation intravenous (IV) opioid analgesic in development for the management of moderate-to-severe acute pain in the hospital and similar settings. The data were highlighted in two poster presentations at the 42nd Annual Regional Anesthesiology and Acute Pain Medicine Meeting hosted in San Francisco by the American Society of Regional Anesthesia and Pain Medicine (ASRA). The data showed significant efficacy of OLINVO in managing moderate-to-severe acute pain, and included head-to-head comparisons to IV morphine suggesting that OLINVO could be a valuable new analgesic option for patients at risk of opioid-related adverse events.

“These data paint a compelling picture of the OLINVO profile compared to intravenous morphine,” said Eugene Viscusi, M.D., Professor of Anesthesiology, Sidney Kimmel Medical College, Thomas Jefferson University. “The results suggest that OLINVO can be dosed to manage moderate-to-severe acute pain, so that patients may titrate opioid dosing as needed. I’m impressed by the performance of the 0.35 mg regimen - the data suggest the potential for improved respiratory safety and gastrointestinal tolerability, without a reduction in the efficacy associated with standard opioid therapy.”

The trials, named APOLLO-1 and APOLLO-2, were Phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of OLINVO. APOLLO-1 evaluated OLINVO in hard tissue pain, following bunionectomy surgery; APOLLO-2 evaluated OLINVO in soft tissue pain following abdominoplasty surgery. Three OLINVO regimens were evaluated; each began with a 1.5 mg IV bolus loading dose, followed by patient-administered doses of 0.1 mg, 0.35 mg, or 0.5 mg as often as every 6 minutes, with supplemental 0.75 mg clinician-administered bolus doses available as often as every hour. Morphine was administered as a commonly used regimen consisting of a 4 mg IV bolus loading dose, followed by patient-administered dosing of 1 mg as often as every 6 minutes, with supplemental 2 mg clinician-administered bolus doses available as often as every hour. The primary objective of each study was to evaluate the analgesic efficacy of OLINVO compared with placebo using a responder analysis; secondary endpoints included comparisons of efficacy, safety and tolerability of OLINVO to morphine. Both studies included measurements of nausea and vomiting, and multiple measures of respiratory safety.

Results of APOLLO-1 (bunionectomy) & APOLLO-2 (abdominoplasty)

Primary endpoint – efficacy vs. placebo

- All three OLINVO regimens (0.1 mg, 0.35 mg, and 0.5 mg on-demand doses) achieved the primary endpoint in both studies, with statistically superior responder rates compared to placebo at 48 hours in the APOLLO-1 hard tissue trial ($p < 0.0001$ for each regimen, adjusted for multiplicity), and at 24 hours in the APOLLO-2 soft tissue trial (adjusted $p < 0.05$ for the 0.1 mg regimen; adjusted $p < 0.001$ for the 0.35 mg and 0.5 mg regimens).

Secondary and exploratory endpoints: comparisons of efficacy, safety, and tolerability vs. IV morphine

- OLINVO demonstrated rapid onset with efficacy superior to morphine in early time points for the 0.35 mg and 0.5 mg regimens in both studies ($p < 0.05$ at 10 through 30 minutes post-dose in APOLLO-1, and $p < 0.05$ at 10 minutes in APOLLO-2).
- The 0.35 mg OLINVO regimen showed comparable pain relief to the morphine regimen over the full dosing period (48 hours in APOLLO-1, 24 hours in APOLLO-2). Patients receiving this regimen in APOLLO-1 administered themselves 49 ± 27 mg of cumulative dose, versus 68 ± 50 mg for the morphine regimen. Patients receiving this regimen in APOLLO-2 administered themselves 21 ± 13 mg of cumulative dose, versus 40 ± 28 mg for the morphine regimen. In both trials, this OLINVO regimen was associated with less frequent adverse events including nausea, vomiting, rescue antiemetic use, respiratory safety events, oxygen desaturation, and use of supplemental oxygen ($p < 0.05$ for antiemetic use and respiratory safety events in APOLLO-1, $p < 0.05$ for vomiting in APOLLO-2).
- The 0.1 mg OLINVO regimen showed significantly lower rates of nausea, vomiting, rescue antiemetic use, respiratory safety events, oxygen desaturation, and use of supplemental oxygen than morphine in both trials ($p < 0.05$ for all), but did not achieve non-inferiority to morphine for analgesic efficacy. In both trials, the 0.5 mg OLINVO regimen showed efficacy comparable to morphine, and rates of gastrointestinal and respiratory events were consistently numerically lower but not statistically different from morphine.

In both studies, OLINVO was generally safe and well-tolerated. The most common drug-related adverse events were nausea, vomiting, headache, and dizziness.

“These results recapitulate our earlier clinical trial results and highlight OLINVO as an innovative new investigational product for hospital patients who require IV opioid analgesics but are at risk from opioid-related adverse events,” said David Soergel, M.D., chief medical officer at Trevena. “Safe, effective, and well tolerated acute pain therapy remains an important unmet need – hospitals are trying to improve patient outcomes, reduce costly delays in recovery, and prevent the transition of acute pain to chronic pain requiring long-term opioid therapy. We believe OLINVO can meet this need. We are on track to submitting our New Drug Application to the FDA in the fourth quarter of this year.”

Details for the poster presentations are as follows:

Title: APOLLO-1: Randomized, Placebo- and Active-Controlled Phase 3 Study Investigating OLINVO (TRV130), a Novel μ Receptor G Protein Pathway Selective (μ -GPS) Modulator, for Management of Moderate to Severe Acute Pain Following Bunionectomy

Poster Number: 3681

A copy of the poster is available on the conference website:

<http://epo.epostersonline.net/ASRASpring17/node/662>

Title: APOLLO-2: A Randomized, Double-Blind, Placebo- and Active-Controlled Phase 3 Study Investigating OLINVO (TRV130), a Novel μ Receptor G Protein Pathway Selective (μ -GPS) Modulator, for the Management of Moderate to Severe Acute Pain

Poster Number: 3682

A copy of the poster is available on the conference website:

<http://epo.epostersonline.net/ASRASpring17/node/667>

About OLINVO™ (oliceridine injection)

OLINVO™ (oliceridine injection) was 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 to date, OLINVO provided rapid and powerful analgesic efficacy while demonstrating a wider therapeutic window compared with 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. If approved, the Company expects OLINVO to be a Schedule II controlled substance.

About moderate-to-severe acute pain management in hospitals

Pain management is essential for patient recovery and discharge from hospitals and ambulatory surgery centers. Despite the use of other approaches to pain relief, IV opioids often remain necessary for treating moderate-to-severe pain: approximately 50 million hospital patients in the U.S. are treated each year with conventional IV opioids. However these medications are associated with important adverse effects: nausea and vomiting occur in approximately 30% of postoperative patients and contribute approximately \$1 billion in U.S. hospital costs; opioid-induced respiratory depression can threaten patient safety and accounts for up to \$28,000 in additional hospital costs per patient. This unmet need is highest for patients whose pain management requires an IV opioid but are at risk from opioid-induced respiratory depression, may suffer surgical complications from post-operative vomiting, or whose recovery may be prolonged by post-operative nausea and vomiting.

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 OLINVO. Trevena also has discovered TRV250, in preclinical development for the treatment of migraine, and TRV734 for pain. 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 interpretation of the top-line results from the APOLLO trials, whether such results paint a compelling picture of OLINVO compared to IV morphine, whether OLINVO can be dosed to manage moderate-to-severe acute pain, whether OLINVO offers the potential for improved respiratory safety and GI tolerability without a reduction in the efficacy of standard IV opioids, whether top-line results from the APOLLO trials will be consistent with the full results of the trials, once available, whether adverse events seen in the APOLLO trials will be consistent with any future adverse events, or whether the APOLLO results recapitulate what the Company saw in earlier clinical trials, and the expected timing of the NDA submission for OLINVO; the uncertainties inherent in conducting clinical trials; expectations for regulatory approvals, including whether the Phase 3 data will support FDA approval of oliceridine for the management of moderate-to-severe pain; 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 physicians, patients, and payers will conclude that the oliceridine development program has shown consistent differentiation from morphine across multiple clinical trials; 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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Source: Trevena Inc.

