

May 22, 2018



# Trevena announces presentations at the American Society of Colon and Rectal Surgeons 2018 Annual Scientific Meeting

## New colorectal surgery data presented from the oliceridine ATHENA Phase 3 open label safety study

CHESTERBROOK, Pa., May 22, 2018 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) today announced two presentations at the American Society of Colon and Rectal Surgeons 2018 Annual Scientific Meeting, held in Nashville, Tennessee, May 19-23.

The first poster highlighted efficacy, safety and tolerability data from 115 colorectal patients from the ATHENA Phase 3 multicenter, open label safety study of Trevena's investigational product oliceridine. In the ATHENA study, oliceridine was administered to 768 patients with moderate-to-severe acute pain caused by medical conditions or surgery. The study was designed to model real-world use of oliceridine in a broad patient case mix and representative surgeries in clinical practice at 41 sites in the United States. The trial included substantial representation of patients at elevated risk for opioid-induced respiratory depression (OIRD), with 32% of patients over 65 years old, and more than 50% with body mass index (BMI) over 30 kg/m<sup>2</sup>. Results of the trial showed that oliceridine can be successfully substituted for conventional IV opioids to manage moderate to severe acute pain.

The second poster presentation reported treatment patterns, burden, and predictors of post-operative nausea/vomiting and OIRD associated with the use of conventional IV opioids to manage acute postoperative pain in approximately 158,000 general and colorectal surgery patients in the Premier Perspectives® Hospital Database. Obesity, respiratory conditions, sleep apnea, and elderly patients were associated with a significantly increased likelihood of opioid-induced adverse events and significantly higher total hospital costs.

"Pain management following colorectal surgery remains an area of high unmet need, because despite widespread use of multimodal analgesia many patients still require substantial doses of IV morphine and then suffer from opioid-related adverse effects," said Anthony Senagore, M.D., Professor of Surgery at Western Michigan University Homer Stryker School of Medicine. "There have been few new analgesic options in decades, so I'm pleased that Trevena has focused on this area with compelling new data on the burden of opioid-related adverse effects, and on the potential for oliceridine to be a new option to use in place of conventional IV opioids."

### Poster presentations: Tuesday, May 22nd

1. e-poster presentation (P499) : Safety of Oliceridine, a G Protein-Biased Ligand at the  $\mu$ -Opioid Receptor, in Patients with Moderate-to-Severe Acute Pain After Colorectal

Surgery: Results from a Phase-3, Open-Label Study. Scheduled to be presented on Tuesday, May 22<sup>nd</sup> from 12:00 – 12:05 pm on Monitor #10 in the e-poster area of the Exhibit Hall in the Music City Center.

2. e-poster presentation (P489) : Prevalence and Burden of Opioid-Induced Respiratory Depression and Postoperative Nausea/Vomiting Associated with the Treatment of Acute Postoperative Pain Following General/Colorectal Surgery. Scheduled to be presented on Tuesday, May 22nd from 12:20-12:25 pm on Monitor #9 in the Exhibit Hall in the Music City Center.

Abstracts may be accessed online at:

[https://www.fascrs.org/sites/default/files/images/image/AM-2018/ascrs18\\_abstract\\_book\\_2\\_for\\_web-2.pdf](https://www.fascrs.org/sites/default/files/images/image/AM-2018/ascrs18_abstract_book_2_for_web-2.pdf)

### **About Oliceridine**

Oliceridine is a next generation IV analgesic for the management of moderate-to-severe acute pain in the hospital and similar settings and has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (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 Phase 2 and Phase 3 clinical trials, 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. The Company expects oliceridine to be a Schedule II controlled substance.

### **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 injection, for the management of moderate-to-severe acute pain, TRV250 for the treatment of acute 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; 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; 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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