

March 5, 2020



# Trevena Announces FDA Has Set PDUFA Date of August 7, 2020 for Oliceridine

*FDA considers NDA resubmission a complete Class 2 response*

*Updated guidance on extended cash runway, funding operations into Q1 2021*

CHESTERBROOK, Pa., March 05, 2020 (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) disorders, today announced that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of the resubmitted New Drug Application (NDA) for IV oliceridine, the Company's lead investigational asset for the management of moderate-to-severe acute pain.

"I am pleased that FDA considers our resubmission to be a complete response to the Agency's 2018 letter. This represents the crucial next step to bringing oliceridine to patients," said Carrie Bourdow, President and Chief Executive Officer of Trevena. "There remains a significant clinical need in the hospital setting for an effective and well-tolerated IV analgesic to help manage patients' moderate-to-severe pain. We are committed to delivering oliceridine to these patients and their healthcare providers, and we look forward to supporting the Agency's review of our application."

In their acknowledgement letter, FDA stated that the Company's resubmission is a complete, Class 2 response to the Agency's action letter dated November 2, 2018. A Prescription Drug User Fee Act (PDUFA) goal date has been set for August 7, 2020.

In addition, the Company today announced that it is updating and extending its cash runway guidance. Cash, cash equivalents, and marketable securities were approximately \$35.8 million as of December 31, 2019, which the Company believes will be sufficient to fund the Company's operating expenses, debt service, and capital expenditure requirements into the first quarter of 2021.

The information above related to the Company's expected operating results for the year ended and as of December 31, 2019, including revenue and cash, cash equivalents, and marketable securities, is preliminary, has not been audited and is subject to change upon completion of the audit of the Company's financial statements as of and for the year ended December 31, 2019.

## **About Oliceridine**

Oliceridine is a G protein-selective mu-opioid receptor agonist in development for the management of moderate-to-severe acute pain in hospitals or other controlled clinical settings where intravenous 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 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 CNS disorders. The Company has four novel and differentiated investigational drug candidates, including IV oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the acute treatment of migraine, and TRV734 for maintenance treatment of opioid use disorder. The Company has also identified TRV045, a novel S1P receptor modulator that may offer a new, non-opioid approach to treating a variety of CNS disorders.

## **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 and trials 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 of any of the Company's investigational drug candidates; the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals, including the Company's assessment of the discussions with FDA, FDA's acknowledgement of the submitted NDA for oliceridine and the timing of FDA's decision on the oliceridine NDA; available funding; 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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