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# Trevena Resubmits New Drug Application for Oliceridine

## Oliceridine is a new chemical entity intended for the management of moderate-to-severe acute pain

CHESTERBROOK, Pa., Feb. 10, 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 it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for IV oliceridine, the Company's lead investigational product for the management of moderate-to-severe acute pain. The Company anticipates a six-month review period by FDA.

The NDA for oliceridine was resubmitted based on the outcome and final minutes of a Type A meeting with FDA, which was conducted to obtain clarity on their Complete Response Letter (CRL). The resubmission package included data from the multi-dose healthy volunteer QT study, nonclinical data that confirmed levels of an inactive metabolite, and drug product validation reports. The resubmission package also specified a maximum daily dose of 27 mg, as previously acknowledged by FDA in the Type A meeting minutes. No efficacy data or additional comparative data versus IV morphine were requested as part of the CRL.

"The resubmission of the oliceridine NDA represents a significant milestone for the program and an important achievement for the company. I am thankful for the team's commitment and diligent work to bring us to this exciting point," said Carrie Bourdow, President and Chief Executive Officer of Trevena. "We appreciate FDA's guidance through the resubmission process and look forward to continuing to work closely with the Agency as they review our application."

**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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