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# Trevena, Inc. Provides Update on Commercial Launch Activities for OLINVYK™ and Announces Anticipated Pipeline Catalysts

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*Build-out of customer-facing team on track for this quarter*

*OLINVYK comprehensive product dossier / health economic model now available to facilitate formulary reviews*

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CHESTERBROOK, Pa., Jan. 06, 2021 (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 provided an update on the U.S. commercial launch for OLINVYK (oliceridine) injection and announced anticipated milestones for 2021.

"We enter 2021 focused on building upon the foundation we laid in 2020 to deliver a successful launch for OLINVYK. I'm pleased by the early interest we've received from hospital physicians and institutions across the country," said Carrie Bourdow, President and Chief Executive Officer of Trevena, Inc. "Additionally, we continue to make exciting progress across our pipeline, with several upcoming catalysts this year."

## **OLINVYK Commercial Launch**

- **OLINVYK commercially available.** The Company has contracted with the three major wholesalers covering the majority of the acute care business. All three vial presentations of OLINVYK (1 mg/1 mL and 2 mg/2 mL single-dose vials; 30 mg/30 mL single-patient-use vials for patient-controlled analgesia) are now available for ordering.
- **Ramp-up of customer engagement activities underway.** Since the approval of OLINVYK, the Company has received inbound interest from a diverse set of institutions and engaged with a number of key opinion leaders who participated in the Phase 3 OLINVYK "real-world" multi-site safety study. Physicians continue to reinforce the value proposition of OLINVYK as a compelling new analgesic option for acute pain patients in the hospital and other controlled clinical settings.

The comprehensive product dossier and detailed health economic model for OLINVYK are now complete and accessible to healthcare decision makers to facilitate formulary inclusion. The health economic model, which highlights OLINVYK versus IV morphine

cost information, is expected to be published in 1H 2021.

In addition, the “Now Available” marketing campaign for OLINVYK has launched, which includes early digital engagement, launch emails to targeted healthcare professionals, and an updated website which provides product ordering and reimbursement information.

- **Build-out of customer-facing team on track for deployment this quarter.**The Company has completed hiring of its medical science liaisons (MSLs) and sales manager team, and it remains on track to complete hiring, training and deployment of its field commercial team this quarter. The Company today announced that it will be targeting 100 formulary acceptances in 2021. In response to the ongoing COVID-19 pandemic, the Company is employing analytics on a local and regional basis to monitor the impact on hospitals and ambulatory surgical centers, and to inform the safe and effective deployment of its customer-facing teams.
- **All required CMS reimbursement submissions and registrations complete.**The Company today announced that all submissions for permanent J- and C-Codes have been submitted to the Centers for Medicare and Medicaid Services (CMS) for OLINVYK. In the interim, as is customary for all new products, customers will use the miscellaneous J- and C-codes for reimbursement. This ensures that OLINVYK can be reimbursed in both the inpatient and outpatient setting until permanent codes are established. Market access resources are now available to customers which support reimbursement of OLINVYK at 95% of Average Wholesale Price (AWP) in advance of pass-through status being decided.

## Pipeline Updates

- **COVID-19 trial for TRV027 on track to report topline data this quarter.**TRV027 is being evaluated in a 60-person trial as a potential treatment for acute lung damage / abnormal blood clotting associated with COVID-19. Imperial College London is sponsoring and funding the study, with additional support through the British Heart Foundation Centre for Research Excellence Award.
- **IND filing for TRV045 on track for 1H 2021.**In December 2020, the Company presented nonclinical data supporting the potential utility of TRV045 to treat a variety of CNS disorders, including epilepsy, chemotherapy-induced peripheral neuropathy, and diabetic peripheral neuropathy. The Company is currently collaborating with the National Institutes of Health (NIH) to evaluate TRV045 in their screening programs for epilepsy and non-addictive treatment of pain.

## About OLINVYK™ (oliceridine) injection

OLINVYK is a new chemical entity approved by the FDA in August 2020. OLINVYK contains oliceridine, a Schedule II controlled substance with a high potential for abuse similar to other opioids. It is indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. OLINVYK is available in 1 mg/1 mL and 2 mg/2 mL single-dose vials, and a 30 mg/30 mL single-patient-use vial for patient-controlled analgesia (PCA). Approved PCA doses are 0.35 mg and 0.5 mg and single bolus doses greater than 3 mg should not be administered. The

cumulative daily dose should not exceed 27 mg. Please see Important Safety Information, including the BOXED WARNING, and full prescribing information at [www.OLINVYK.com](http://www.OLINVYK.com).

## **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 one approved product in the United States, OLINVYK™ (oliceridine) injection, indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. The Company also has four novel and differentiated investigational drug candidates: TRV250 for the acute treatment of migraine, TRV734 for maintenance treatment of opioid use disorder, and TRV027 for acute lung injury / abnormal blood clotting in COVID-19 patients. 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.

For more information, please visit [www.Trevena.com](http://www.Trevena.com)

## **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, commercialization of approved drug products and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "objective," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," "ongoing," or the negative of these terms or 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 commercialization of any approved drug product, 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 the FDA or other regulatory agencies about any and all of its programs; uncertainties related to the commercialization of OLINVYK; available funding; uncertainties related to the Company's intellectual property; uncertainties related to the ongoing COVID-19 pandemic, 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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