Trevena Initiates Phase 1 Multiple Ascending Dose Study of TRV734 for Acute and Chronic Pain

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)-- Trevena, Inc. (NASDAQ: TRVN), a clinical-stage pharmaceutical company and leader in the discovery and development of G protein coupled receptor (GPCR) biased ligands, today announced the initiation of the next Phase 1 trial for TRV734, a novel drug candidate in development as an orally administered treatment for moderate-to-severe acute and chronic pain. TRV734 is being developed to optimize analgesia while minimizing on-target gastrointestinal and central nervous system adverse effects through its novel biased ligand mechanism at the mu-opioid receptor. TRV734 takes advantage of the same receptor specificity mechanism as Trevena's Phase 2 clinical compound TRV130, an intravenous mu-opioid G protein biased ligand being developed for acute postoperative pain.

The Phase 1 trial will evaluate the safety, tolerability, pharmacodynamics (PD) and pharmacokinetics (PK) of TRV734 given as a single dose and as multiple ascending doses in healthy volunteers. The aim of this study is to support Phase 2 development. Top line data are expected in the first half of 2015.

The study will be conducted in two parts and enroll a total of approximately 72 healthy volunteers. Part A will assess the safety, tolerability, PD and PK of single 125 mg doses of TRV734 in an open-label, randomized, three-period crossover study in which subjects are fasted, fed a standard meal, or fed a high-fat meal. This portion of the study is designed to explore how changes in absorption may modify the performance of TRV734 and to identify the best administration paradigm for Part B.

Part B of the trial will assess the safety, tolerability, PD and PK of multiple ascending doses of TRV734 in a double-blind, double-dummy, randomized, active- and placebo-controlled adaptive study. Oxycodone immediate release 10 mg will be used as a benchmark for a variety of pharmacodynamic measures intended to evaluate the analgesic and adverse effect profile of TRV734.

"This study builds on our recent positive Phase 1 data, and will explore dose regimens of TRV734 using a series of validated experimental measures to support subsequent Phase 2 development," said Maxine Gowen, Ph.D., chief executive officer. "We believe that TRV734 could replace current opioid analgesics by offering improved pain relief with reduced incidence and severity of opioid-related adverse effects."

About TRV734

The mu-opioid receptor is a well-established target for effective analgesics such as fentanyl and morphine, which are unbiased mu-opioid agonists. TRV734 is a biased ligand at the mu-opioid receptor, activating the G protein pathway, associated with analgesia, without activating the mu-opioid beta-arrestin pathway, associated with respiratory depression and constipation in preclinical studies. TRV734 takes advantage

of the same novel biased ligand mechanism at the mu-opioid receptor as TRV130, the company's Phase 2 intravenous clinical candidate which has shown promising differentiation versus morphine.

About Trevena

Trevena, Inc. is a clinical stage biopharmaceutical company that discovers, develops and intends to commercialize therapeutics that use a novel approach to target G protein coupled receptors, or GPCRs. Using its proprietary product platform, Trevena has identified and advanced three differentiated biased ligand product candidates into the clinic – TRV027 to treat acute heart failure, TRV130 to treat moderate-to-severe acute pain intravenously, and TRV734 to treat moderate-to-severe acute and chronic pain orally. Trevena also is advancing additional product candidates in its portfolio, including a preclinical program focused on central nervous system indications.

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 whether the study design of the Phase 1 multiple ascending dose study for TRV734 will yield the intended results or support Phase 2 development of this molecule and whether TRV734 could ultimately replace current opioid analgesics by offering improved pain relief with reduced incidence and severity of opioid-related adverse effects; the uncertainties inherent in conducting clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials will be indicative of the results of future trials; expectations for regulatory approvals; availability of funding sufficient for the company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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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