

January 6, 2015



Trevena Initiates Second Phase 2b Study of TRV130 for Acute Postoperative Pain

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)-- Trevena, Inc. (NASDAQ: TRVN), a clinical stage pharmaceutical company focused on the discovery and development of biased ligands targeting G protein coupled receptors (GPCRs), today announced the initiation of a Phase 2b clinical trial of TRV130 for acute postoperative pain in patients following abdominoplasty surgery. TRV130 is a small molecule biased ligand at the mu-opioid receptor that Trevena is developing as a first-line intravenous treatment for patients experiencing moderate-to-severe acute pain.

In this multicenter, randomized, double-blind, placebo- and active-controlled clinical trial, TRV130's efficacy and tolerability will be evaluated in the management of postoperative pain following abdominoplasty surgery, a representative soft tissue surgery. The study will include morphine as a benchmark and utilize a flexible dose, patient-controlled analgesia (PCA) administration regimen intended to optimize treatment and reflect the as-needed dosing most commonly used with post-operative opioid analgesics. Approximately 200 patients will be assigned randomly to a post-operative regimen of TRV130, placebo, or morphine, in a 2:1:2 ratio respectively, for 24 hours after surgery, beginning when post-operative pain becomes moderate or severe in intensity.

"This study complements our highly successful Phase 2 study of TRV130 following bunionectomy surgery by evaluating TRV130 following a soft tissue surgery," said Maxine Gowen, Ph.D., chief executive officer. "We believe that the use of patient-controlled analgesia will provide another important measure of TRV130's therapeutic profile as compared to morphine by allowing patients to optimize dosing of both drugs."

Treatment in the study will begin with a double-blind loading dose of TRV130, morphine or placebo, after which each patient can self-administer lower doses as needed for pain relief. This allows patients to increase dosing if analgesia is insufficient and to limit dosing if side effects are intolerable. After the first hour of treatment, the investigator may increase the strength of the available patient-administered dose by 50% in a double-blind fashion if additional pain relief is needed.

The primary endpoint of this study is the time-weighted average change from baseline in the numeric pain rating scale scores over the 24-hour assessment interval for TRV130 compared to placebo. TRV130 will be compared to morphine as a secondary endpoint. Other secondary assessments include evaluation of pain scores over shorter assessment intervals; rates of opioid-related adverse effects as measured by oxygen saturation, nausea numeric rating scale, and rescue antiemetic utilization; and patient satisfaction using the Patient Global Assessment of the Method of Pain Control. This study will progress in parallel with the Company's ongoing preparations for Phase 3 clinical trials of TRV130, which are expected to begin in the first quarter of 2016. Top-line data from this Phase 2 study are expected in mid-2015.

About TRV130

TRV130 was designed to optimize opioid receptor pharmacology to deliver an improved analgesic profile. TRV130 is a biased mu-opioid receptor ligand, a novel opioid receptor modulator which in preclinical studies activated analgesic signals while avoiding signals that can interfere with analgesia and promote respiratory depression and gastrointestinal dysfunction. The company recently reported top-line data for a Phase 2a/b trial comparing TRV130 to placebo and morphine following bunionectomy surgery. In this trial TRV130 demonstrated superior efficacy to a standard dose of morphine, with average reduction in numeric pain rating scale up to 6 points from a baseline of 7 points. This efficacy was achieved without any serious adverse events and without significant respiratory depression as measured by oxygen desaturation. Trends in respiratory depression were worse for morphine than for TRV130. Doses of TRV130 that showed superior efficacy to morphine had similar tolerability to morphine. Trevena believes that TRV130 may have an improved profile compared to currently used opioid analgesics and could offer enhanced pain relief with a reduced burden of opioid-related adverse events. Trevena anticipates that the initial market opportunity for TRV130 will be in the acute care settings, with a focus on postoperative pain in the hospital.

About moderate-to-severe acute pain

Mu-opioid receptor agonists such as morphine and fentanyl are the most effective class of analgesics currently available and are the standard of care in postoperative pain; however, in published national surveys, a significant proportion of surgical patients have reported inadequate pain relief despite use of opioid analgesics. Opioid related adverse effects such as respiratory depression, nausea and vomiting, and constipation and postoperative ileus are frequently dose-limiting, complicating pain management and increasing the burden of care.

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 is developing four biased ligand product candidates it has identified - TRV027 to treat acute heart failure (Phase 2b), TRV130 to treat moderate-to-severe acute pain intravenously (Phase 2b), TRV734 to treat moderate-to-severe acute and chronic pain orally (Phase 1), and TRV250 for treatment-refractory migraine and other CNS disorders (Preclinical).

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, its future operations, clinical development of its therapeutic candidates, its plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "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 whether ongoing or planned clinical trials will yield anticipated results, including whether the use of patient-controlled analgesia in the Phase 2b

study of TRV130 for acute postoperative pain will provide another important measure of TRV130's therapeutic profile as compared to morphine; whether the Company's interpretation of the results of clinical trials will be indicative of the results of any future trials; the availability and timing of data from ongoing 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; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates; and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission on March 20, 2014 and other filings the Company makes with the Securities and Exchange Commission from time to time. In addition, the forward-looking statements included in this press release represent the Company's views 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, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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Source: Trevena, Inc.