



Capnia Enrolls First Patient in Phase 2 Clinical Trial Evaluating Nasal CO₂ for the Symptomatic Treatment of Trigeminal Neuralgia

February 25, 2016

REDWOOD CITY, Calif., Feb. 25, 2016 (GLOBE NEWSWIRE) -- Capnia, Inc. (NASDAQ:CAPN), a diversified healthcare company that develops and commercializes innovative diagnostics, devices and therapeutics addressing unmet medical needs, today announced enrollment of the first patient in a Phase 2 clinical trial evaluating nasal, non-inhaled carbon dioxide nasal CO₂ (nasal CO₂) for the symptomatic treatment of trigeminal neuralgia (TN). In December 2015, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to the Company's nasal CO₂ technology for the treatment of TN.

The multi-center, placebo-controlled, single-blind clinical trial is designed to enroll up to 50 patients with TN. The primary efficacy endpoint of the trial is pain relief as reported on a visual analog scale (VAS) in a subject diary, assessed through 24 hours from initial dose. Jason Sheehan, M.D., Ph.D., Professor of Neurological Surgery and Neuroscience, University of Virginia Medical Center, is the principal investigator of the study. Capnia expects to report top-line data from this trial by the end of 2016.

"Trigeminal neuralgia is an extreme, sporadic, burning or shock-like facial pain that can last anywhere from a few seconds to many minutes per episode. If inadequately controlled, the pain associated with trigeminal neuralgia can be debilitating," said Dr. Sheehan. "Many of the pharmaceutical alternatives for treating TN lose effectiveness over time, or they yield pain relief but with significant unpleasant side-effects. We are eager to evaluate Capnia's nasal CO₂ technology in a controlled setting as we pursue a new treatment paradigm for patients suffering from TN-related pain."

"Enrollment of the first patient in this pilot clinical study is an important milestone for the therapeutic nasal CO₂ development program for the treatment of TN," said Anish Bhatnagar, M.D., Chief Executive Officer of Capnia. "We continue to execute on our strategy of bringing novel therapies based on our nasal CO₂ technology to patients as quickly as possible."

Capnia's therapeutic technology uses nasal, non-inhaled carbon dioxide, delivered at a low-flow rate into the nasal cavity to alleviate symptoms of allergies as well as pain disorders related to the trigeminal nerve. Capnia developed Serenz™ for the treatment of allergy symptoms, and has completed multiple clinical trials for the treatment of pain (such as migraine) using this technology. The use of Capnia's nasal CO₂ product for the treatment of TN is supported by preclinical and clinical data demonstrating that CO₂ may inhibit sensory nerve activation, may inhibit subsequent release of neuropeptides and may alleviate trigeminally-mediated pain. Collectively, these data suggest that nasal CO₂ may provide relief of symptoms associated with TN.

For more information about the Pilot clinical trial please visit [ClinicalTrials.gov \(NCT02473016\)](https://clinicaltrials.gov/ct2/show/study/NCT02473016).

About Trigeminal Neuralgia

Trigeminal neuralgia (TN) is a clinical condition characterized by debilitating pain in regions of the face innervated by one or more divisions of the trigeminal nerve. The pain is typically described as intense, sharp and stabbing, and is often described as one of the most painful conditions known to humans. It may develop without apparent cause or be a result of another diagnosed disorder, including multiple sclerosis and herpes zoster.

About Capnia

Capnia, Inc. is a diversified healthcare company that develops and commercializes innovative diagnostics, devices and therapeutics addressing unmet medical needs. Capnia's lead commercial product, CoSense, is based on the Sensalyze™ Technology Platform. It is a portable, non-invasive device that rapidly and accurately measures carbon monoxide (CO) in exhaled breath. CoSense has 510(k) clearance for sale in the U.S. and has received CE Mark certification for sale in the European Union. CoSense is used for the monitoring of CO from internal sources (such as hemolysis, a dangerous condition in which red blood cells degrade rapidly), as well as external sources (such as CO poisoning and smoke inhalation). The initial target market is newborns with jaundice that are at risk for hemolysis, comprising approximately three million births in the U.S. and European Union. The Company's commercial, neonatology-focused product line also includes innovative pulmonary resuscitation solutions, including the NeoPIP™ Infant T-Piece Resuscitator and Universal T-Piece Circuit consumables. Capnia's proprietary therapeutic technology uses nasal, non-inhaled CO₂ and is being evaluated to treat the symptoms of allergies, as well as the trigeminally-mediated pain conditions such as cluster headache, trigeminal neuralgia and migraine.

Forward-Looking Statements

This press release contains forward-looking statements that are subject to many risks and uncertainties. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned product development, renewed focus on our therapeutic business and our ability to report data from our TN Pilot clinical trial in 2016.

We may use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained herein, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation. As a result of these factors, we cannot assure you that the forward-looking statements in this presentation will prove to be accurate. Additional factors that could materially affect actual results can be found in Capnia's

Form 10-Q filed with the Securities and Exchange Commission on November 12, 2015, including under the caption titled "Risk Factors." Capnia expressly disclaims any intent or obligation to update these forward looking statements, except as required by law.

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