



Capnia Granted Orphan Designation for Nasal CO₂ for the Treatment of Trigeminal Neuralgia

December 21, 2015

REDWOOD CITY, Calif., Dec. 21, 2015 (GLOBE NEWSWIRE) -- Capnia, Inc. (NASDAQ:CAPN), a diversified healthcare company that develops innovative diagnostics, devices and therapeutics addressing unmet medical needs, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to the Company's nasal, non-inhaled carbon dioxide (nasal CO₂) technology for the treatment of trigeminal neuralgia (TN).

"Receiving orphan designation from the FDA is a key step in the advancement of our nasal CO₂ technology, and speaks to the need for new treatment options for the debilitating pain caused by TN, where limited alternatives currently exist," 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 target local trigeminal nerve endings. Multiple clinical trials for the treatment of allergies as well as pain conditions (such as migraine) have been completed using this technology. The use of nasal CO₂ for the treatment of TN is supported by data demonstrating that CO₂ may inhibit sensory nerve activation, subsequent release of neuropeptides and alleviate trigeminally-mediated pain. Collectively, these data suggest that nasal CO₂ may provide relief of symptoms associated with TN.

In the U.S., under the Orphan Drug Act, the FDA's Office of Orphan Products Development grants orphan drug status to a drug intended to treat a rare disease or condition, which is generally a disease that affects fewer than 200,000 individuals in the country. The designation provides Capnia's nasal CO₂ therapeutic with certain benefits, including seven years of U.S. market exclusivity in the specified indication if Capnia complies with certain FDA requirements. Additional incentives for Capnia include tax credits related to qualified clinical trial expenses and a exemption from FDA application fees.

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 innovative diagnostics, devices and therapeutics addressing unmet medical needs. 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. 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.

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 advance our nasal CO₂ technology for TN.

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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