Capnia Applies for Orphan Drug Designation in the U.S. for the Treatment of Trigeminal Neuralgia

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REDWOOD CITY, Calif., Jan. 8, 2015 /PRNewswire/ -- Capnia, Inc. (NASDAQ: CAPN), focused on the development of novel diagnostics and therapeutics based on its proprietary technologies for precision metering of gas flow, today announced that it has submitted an application to the U.S. Food and Drug Administration (FDA) requesting Orphan Drug Designation for its nasal, non-inhaled carbon dioxide (nasal CO_2) technology for the treatment of trigeminal neuralgia (TN).

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.

Capnia's therapeutic technology uses nasal, non-inhaled CO_2, 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 CO_2 product for the treatment of TN is supported by preclinical and clinical data demonstrating that CO_2 may inhibit sensory nerve activation, subsequent release of neuropeptides and alleviate trigeminally mediated pain. Collectively, these data suggest that nasal CO_2 may provide relief of symptoms associated with TN.

"Treatment of the debilitating pain of TN during an attack is a significant unmet need. Available drug therapies need chronic administration of drugs with potentially substantial side effects. Surgical procedures may alleviate pain in some patients but carry risk of post-surgical complications. Filing this application with the FDA is an important step for the advancement of the nasal CO_2 development program," said Anish Bhatnagar, M.D., Chief Executive Officer of Capnia. "Orphan designation is part of our strategy to bring our proprietary nasal CO_2 technology to patients as rapidly as possible."

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. Upon approval, the designation would provide Capnia's nasal CO_2 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 would include tax credits related to qualified clinical trial expenses and a possible exemption from FDA application fees.

More About Trigeminal Neuralgia

The International Headache Society describes TN as a disorder characterized by recurrent unilateral brief electric shock-like pains, abrupt in onset and termination, limited to the distribution of one or more divisions of the trigeminal nerve and triggered by innocuous stimuli. There may or may not be, additionally, persistent background facial pain of moderate intensity. In the U.S., Capnia estimated in its Orphan Drug application filed with the FDA that approximately 100,000 people are afflicted with TN.

About Capnia

Capnia, Inc. develops and commercializes novel diagnostics and therapeutics based on its proprietary technologies for precision metering of gas flow. Capnia's lead diagnostic product is CoSense®, which aids in the diagnosis of hemolysis, a dangerous condition in which red blood cells degrade rapidly. CoSense, based on the Sensalyze™ Technology Platform, is a portable, non-invasive device that rapidly and accurately measures carbon monoxide in exhaled breath. CoSense has 510(k) clearance from the U.S. FDA and was launched in the U.S. in October 2014. CoSense has also received CE Mark approval for sale in the European Union. Capnia's proprietary therapeutic technology uses nasal, non-inhaled CO_2 to treat symptoms of allergies, as well as the trigeminally mediated pain conditions such as cluster headache, TN 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 and clinical trials and the ability to get Orphan Drug Designation approval from the FDA.

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 S-1 filed with the Securities and Exchange Commission on November 14, 2014, 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.

Capnia Contact:
David O'Toole
Chief Financial Officer
Capnia, Inc.
(650) 353-5146
dotoole@capnia.com

Investor Relations Contact:
Michelle Carroll/Susie Kim
Argot Partners
(212) 600-1902
michelle@argotpartners.com
susie@argotpartners.com

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