

# Capnia Announces Enrollment of First Patient in Clinical Trial for Treatment of Cluster Headache

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REDWOOD CITY, Calif., July 22, 2015 (GLOBE NEWSWIRE) -- Capnia, Inc. (NASDAQ:CAPN), focused on the development and commercialization of novel products based on its proprietary technologies for precision metering of gas flow, today announced enrollment of the first patient in an investigator-sponsored clinical trial evaluating Capnia's proprietary nasal, non-inhaled carbon dioxide (nasal CO<sub>2</sub>) technology for the treatment of cluster headaches.

This pilot, single-center clinical trial is being conducted under a collaboration agreement announced earlier this year between Capnia and Clinvest®, a clinical research organization and division of Banyan Group, Inc., and is designed to enroll 25 patients with episodic cluster headaches. The primary efficacy endpoint of the trial is the greatest change from pre-treatment headache pain intensity to post treatment. Roger K. Cady, M.D., founder of the Headache Care Center and Chief Executive Officer of Clinvest, will serve as principal investigator for the trial. Capnia expects to report top-line data from this trial in 2016.

"The term 'headache' does not adequately convey the severity of pain experienced by cluster headache patients, which may be the most painful condition known to medical science, but with few effective treatments currently available," said Dr. Cady. "This trial is designed to explore Capnia's nasal CO<sub>2</sub> technology in a robust scientific setting, and I look forward to more fully elucidating its potential in this rare, but debilitating neurological disorder."

"At Capnia, we are working to rapidly advance our therapeutic technology, and the commencement of this clinical trial evaluating our nasal CO<sub>2</sub> technology in cluster headache is an important step toward that goal," said Anish Bhatnagar, M.D., Chief Executive Officer of Capnia. "We believe our nasal CO<sub>2</sub> technology has the potential to serve as a novel therapeutic option for cluster headache, which remains a significant unmet need."

For more information on this clinical trial please visit: https://clinicaltrials.gov/ct2/show/NCT02381795

#### **About Cluster Headache**

Cluster headaches affect approximately 0.2% of the population, and are characterized by recurring bouts of excruciating pain in one side of the head. Episodes of pain typically last from 15 minutes to three hours. They can occur several times a day over several months of time before remission. However, the same pattern often recurs multiple times over their lifetime. Approximately 10 to 15% of cluster patients have "chronic" cluster headache, with continuing pain with no remission. The pain of cluster headache may be significantly greater than other conditions, such as severe migraine.

# About Nasal CO<sub>2</sub> Technology

Capnia's therapeutic technology uses nasal, non-inhaled CO<sub>2</sub>, delivered at a low-flow rate into the nasal cavity. The potential indications include alleviation of symptoms of allergies as well as trigeminally mediated pain disorders such as cluster headache, migraine and trigeminal neuralgia (TN). Capnia has completed multiple clinical trials for the treatment of the symptoms of allergic rhinitis as well as conditions such as migraine using this technology. The use of Capnia's nasal CO<sub>2</sub> product for the treatment of cluster headache, migraine and TN is supported by preclinical and clinical data demonstrating that CO<sub>2</sub> may inhibit sensory nerve activation, subsequent release of neuropeptides and alleviate trigeminally mediated pain.

### **About Capnia**

Capnia, Inc. develops and commercializes novel products based on its proprietary technologies for precision metering of gas flow. Capnia's lead 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. 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 and clinical trials, the primary efficacy endpoint of the cluster headache trial will be reached and that we will report top-line data from this 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-K filed with the Securities and Exchange Commission on March 13, 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.

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

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