

# Capnia Receives Re-Certification of European CE Mark for Serenz® for the Treatment of Nasal Allergy Symptoms

# March 14, 2016

## Company on track to initiate pilot sales through European Union pharmacies in second quarter 2016

REDWOOD CITY, Calif., March 14, 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 that the Company has obtained re-certification of the CE Mark for Serenz, its nasal, non-inhaled CO<sub>2</sub> product for the treatment of symptoms related to allergic rhinitis (AR or nasal allergies). CE Mark certification is a conformance mark granted by the European Commission for the sale of certain medical devices without restriction across the 28 member nations of the European Union (EU). With the CE Mark, the Company plans to move forward with pilot sales of Serenz to pharmacies in the EU during the second quarter of 2016. The Company intends to provide limited supplies of Serenz to a number of pharmacies with the intent of gathering commercial feedback on the product in preparation of a possible full launch of Serenz.

"CE Mark certification is an essential regulatory milestone as we advance toward commercialization of Serenz in Europe, and we look forward to initiating pilot sales to EU pharmacies during the second quarter of 2016," said Anish Bhatnagar, MD, Chief Executive Officer of Capnia. "AR is typically an episodic disorder with intermittent symptoms. However, there is no treatment currently available that provides truly rapid relief of all nasal symptoms. We believe that Serenz has an ideal profile for an as-needed therapeutic for AR and may provide advantages over regularly dosed, slow to act currently marketed products."

A CE Mark certification was previously granted to the Company in December 2011 for the marketing of Serenz in the EU.

#### About Serenz

Serenz is a hand-held device that is designed to provide rapid relief from the symptoms related to AR. In clinical trials to date, Serenz has shown relief of symptoms related to allergies within 30 minutes and a mild side effect profile. The Serenz technology is based upon the observation that non-inhaled  $CO_2$  delivered at a low-flow rate into the nasal cavity alleviates the symptoms related to allergies. Capnia's nasal, non-inhaled CO<sub>2</sub> is currently in Phase 2 development in the U.S.

## 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<sup>™</sup> 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<sup>™</sup> Infant T-Piece Resuscitator and Universal T-Piece Circuit consumables. Capnia's proprietary therapeutic technology uses nasal, non-inhaled CO<sub>2</sub> 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 launch pilot sales in the European Union in the second quarter of 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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