



Capnia and Essentialis Announce Merger to Create Rare Disease Therapeutics Company

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Combined Company to Focus on Advancing Novel, Late-Stage Asset for the Treatment of Prader-Willi Syndrome, a Devastating, Orphan Disease

Enrollment in a Phase II/III Clinical Trial Expected to Begin in Second Half of 2017

\$8 Million Concurrent Financing; Sufficient to Fund Development Plan Through Key Value-Creating Milestones

Essentialis

REDWOOD CITY, Calif. and CARLSBAD, Calif., Dec. 27, 2016 (GLOBE NEWSWIRE) -- Capnia, Inc. (NASDAQ:CAPN) and privately-held Essentialis, Inc. today announced their entry into a definitive merger agreement to create a rare disease therapeutics company. The combined company will be well-positioned to advance diazoxide choline controlled release tablet (DCCR), a once-daily oral tablet for the treatment of patients with Prader-Willi syndrome (PWS). PWS is a rare complex genetic neurobehavioral/metabolic disease. The clinical features of the disease include hyperphagia (unrelenting hunger), as well as metabolic, endocrine, cognitive and behavioral complications resulting in significant morbidity and premature death.

Upon closing of the merger, Capnia expects to issue shares of common stock at \$0.96 per share to a syndicate comprised of current and new investors for gross proceeds of \$8.0 million. These funds would be used to execute a planned Phase II/III clinical study evaluating the efficacy and safety of DCCR for the treatment of patients with PWS. This study is expected to commence in the second half of 2017.

Anish Bhatnagar, MD, Chief Executive Officer of Capnia, stated, "We are excited to combine the strengths of these two dynamic organizations to create a leading rare disease therapeutics company that has the potential to bring a novel drug candidate to patients suffering with PWS, a devastating, often life-threatening disorder. While this transaction represents a new strategic direction for Capnia, it offers the potential of a highly-promising, late-stage clinical asset for a metabolic disorder for which no effective treatments currently exist. The new company, together with the \$8.0 million in financing, will be well-positioned to maximize long-term value for all its stakeholders."

"Prader-Willi syndrome is a rare, genetic neurobehavioral/metabolic disorder, which results in diminished quality of life, as well as a risk of premature death for the patient and substantial caregiver burden," said Neil M. Cowen, PhD, MBA, President and Chief Scientific Officer of Essentialis. "DCCR has a long and established safety record and has been shown in a Phase II trial to positively impact hyperphagia, which is perhaps the biggest obstacle to PWS patients and their families being able to lead normal lives. Statistically significant benefits were also observed in body composition and aggressive, threatening and destructive behaviors. Importantly, DCCR's safety has been extensively addressed in multiple clinical trials and its parent molecule has a decades-long track record of safety and tolerability. We are eager to advance DCCR through its next phase of development, with the goal of addressing the highest priority unmet medical needs of PWS and improving the quality of life of PWS patients and their families."

Key strategic benefits of the merger include:

- **Accelerating development of a late-stage clinical asset with a strong product profile.** The combined company will be focused on advancing oral, once-daily DCCR through a pivotal Phase II/III clinical trial. The DCCR program is supported by a well-established safety profile of its parent molecule and prior experience with DCCR in other metabolic conditions. Preliminary efficacy data have shown significant and clinically-meaningful reductions in hyperphagia, changes in body composition and behavioral improvements in subjects with PWS.
- **Well capitalized, including through key value-inflection points.** With the \$8.0 million in financing, the combined company is expected to have a cash runway beyond key value-inflection points, through top-line results from the Phase II portion of the trial.
- **Proprietary, high-value, orphan product.** DCCR is protected by extensive intellectual property and has been granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of PWS.
- **Substantial Value Creation.** As a combined entity, there is potential to create additional, long-term shareholder value through the development of DCCR in PWS, and other orphan indications.

Key Terms of the Merger

Under the terms of the merger agreement, upon the completion of the transaction, Capnia will acquire all outstanding shares of Essentialis. The merger transaction has been approved by the boards of directors of both companies and is expected to close during the first quarter of 2017, subject to customary closing conditions, including Capnia shareholder approval. The combined company will be led by Anish Bhatnagar, MD, Capnia's Chief Executive Officer. Dr. Cowen will join the combined company as Senior Vice President of Drug Development. David O'Toole, Capnia's Senior Vice President and Chief Financial Officer, will continue as CFO of the combined company. The Board of Directors of the combined company is expected to consist of nine directors, with six current Capnia directors and three current Essentialis directors.

Capnia intends to evaluate alternatives for its legacy products and product candidates, including CoSense® ETCO Monitor, Serenz® Allergy Relief, and its portfolio of innovative pulmonary resuscitation solutions for the neonatal market.

Clinical Data for DCCR in PWS

In a recently completed, open-label study with a randomized placebo-controlled withdrawal phase (clinical study PC025; n=13), DCCR demonstrated an approximately 32% reduction in hyperphagia (p=0.003), a highly significant and clinically relevant improvement on the highest priority symptom of the disorder. The mean effect on hyperphagia persisted for over 3 months for DCCR-treated individuals who continued on study through the double-blind treatment phase, and regressed back towards baseline in those randomized to placebo. In addition, statistically significant improvements were seen in other endpoints such as aggressive behaviors, body fat, lean body mass and cardiovascular risk factors. There were no new safety findings in this study and the adverse events profile (consisting mostly of mild to moderate AEs) was consistent with the known profile of diazoxide, DCCR's parent molecule. These results were presented at the recent International Prader-Willi Syndrome Organization (IPWSO) meeting.

This single-center study was conducted at the University of California, Irvine under the direction of Dr. Virginia Kimonis, a nationally-renowned expert in PWS and other serious and complicated pediatric genetic disorders.

About PWS

PWS is a rare and complex genetic disorder affecting appetite, growth, metabolism, cognitive function and behavior. In the US, it is estimated that one in 12,000 to 15,000 people has PWS. This disorder is typically characterized by low muscle tone, short stature (when not treated with growth hormone), incomplete sexual development, cognitive disabilities, behavioral problems, and hyperphagia, a chronic feeling of insatiable hunger. Combined with a reduced metabolism, PWS can lead to excessive eating and without effective limitations on access to food, can result in morbid obesity. In a global survey conducted by the Foundation of Prader-Willi Syndrome, 96.5% of respondents (parent and caregivers) rated hyperphagia as the most important unmet need.

About Diazoxide Choline Controlled Release

Diazoxide Choline Controlled Release (DCCR) is a novel, proprietary controlled-release, crystalline salt formulation of diazoxide which is administered as a once-daily tablet. The parent molecule, diazoxide, as an oral suspension, has been effective and used safely for decades as a first line therapy in a range of rare conditions such as hyperinsulinemic hypoglycemia in neonates, children and adults. The DCCR development program is supported by positive data from two completed Phase II clinical studies and six completed Phase I clinical studies in various metabolic indications. DCCR was granted Orphan Drug Designation for the treatment of PWS by the FDA on May 13, 2014.

About Capnia

Capnia is a leading provider and developer of innovative healthcare products to be used for the screening, detection and treatment of medical conditions. Capnia's flagship products are based on its proprietary technologies, which utilize precision metering of gas flow. Capnia currently markets Serenz® Allergy Relief in the UK. The CoSense® ETCO Monitor measures ETCO, which can be used to detect hemolysis and the Infant Solutions product line, including innovative pulmonary resuscitation devices for neonates and infants, are marketed globally. Capnia is also clinically evaluating its nasal, non-inhaled CO₂ technology to treat trigeminally-mediated pain conditions such as cluster headache and trigeminal neuralgia. For more information, please visit www.capnia.com.

About Essentialis

Essentialis is a privately-held clinical-stage pharmaceutical company focused on the development of breakthrough medicines for the treatment of rare metabolic diseases where there is increased mortality and risk of cardiovascular and endocrine complications.

Capnia's 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 ability to complete the merger and initiate the Phase II/III trial in the second half of 2017.

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 14, 2016, 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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Capnia, Inc.