Soleno Therapeutics Announces Successful Completion of FDA Meeting for DCCR in Prader-Willi Syndrome

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- Positive guidance received on key elements of Phase III program
- Company expects to initiate pivotal Phase III clinical trial by year-end 2017
- DCCR has orphan designation for the treatment of PWS in the US

REDWOOD CITY, Calif., July 05, 2017 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (NASDAQ:SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that it has received the minutes from a scientific advice meeting from the U.S. Food and Drug Administration (FDA) regarding Diazoxide Choline Controlled-Release (DCCR) for the treatment of Prader-Willi syndrome (PWS). PWS is a rare and complex genetic neurobehavioral/metabolic disorder affecting appetite, growth, metabolism, cognitive function, and behavior. DCCR has Orphan Designation for the treatment of PWS in the United States.

As part of the briefing information for the meeting, Soleno submitted data from a Phase II study of DCCR in PWS patients as well as data from other studies conducted with DCCR. There was general agreement regarding several key aspects of the proposed development plan.

The FDA expressed support for change in hyperphagia score (without a change in weight) compared to placebo as the primary endpoint for the study. In addition, based on the data provided in the meeting briefing information, the dosing paradigm proposed by the Company for the study was accepted. The FDA proposed, and Soleno agreed, that the duration of the randomized, double-blind, placebo-controlled study should be shorter (3-4 months) and that DCCR safety information could be obtained in a long-term, safety extension study.

Based on these discussions, Soleno will finalize the design of a Phase III, randomized, double-blind placebo-controlled study which will treat approximately 100 patients. The study is expected to start, subject to final agreement by the FDA, at the end of 2017 and will take approximately 9-12 months to complete. Additional regulatory input is being sought on various aspects of this late-phase development program.

“We are pleased with the positive outcome of this meeting and the constructive guidance received from the FDA,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. “We now have a clearer understanding of the regulatory pathway for DCCR in the U.S. for the treatment of PWS. The use of change in hyperphagia score compared to placebo as the primary endpoint, and the potential for the Phase III trial to be shorter than originally proposed, are encouraging outcomes from this meeting. We remain committed to the development of DCCR, which, if approved, could provide the desperately needed treatment for this life-threatening condition. Based on the clinical data generated to date, we believe DCCR has the potential to be a safe and effective treatment for PWS patients, and look forward to initiating this Phase III trial before the end of 2017.”

About PWS

PWS is a rare and complex genetic neurobehavioral/metabolic disorder affecting appetite, growth, metabolism, cognitive function and behavior. The committee on genetics of the American Academy of Pediatrics states PWS affects both genders equally and occurs in people from all geographic regions: its estimated incidence is one in 15,000 to 25,000 live births. This disorder is typically characterized by hyperphagia, a chronic feeling of insatiable hunger, behavioral problems, cognitive disabilities, low muscle tone, short stature (when not treated with growth hormone), the accumulation of excess body fat, developmental delays, and incomplete sexual development. Hyperphagia can lead to significant morbidities (i.e., stomach rupture, obesity, diabetes, cardiovascular disease) and mortality (i.e., choking, accidental death due to food seeking behavior, etc.). In a global survey conducted by the Foundation for Prader-Willi Research, 96.5% of respondents (parent and caregivers) rated hyperphagia, which is the unrelenting hunger that severely diminishes the quality of life for patients and their families, as the most important or a very important symptom to be relieved by a new medicine. There are currently no approved therapies to treat the hyperphagia/appetite, metabolic, cognitive function, or behavioral aspects of the disorder. DCCR has received Orphan Drug Designation from the US FDA for the treatment of PWS.

About Diazoxide Choline Controlled-Release Tablet

Diazoxide choline controlled-release tablet is a novel, proprietary controlled-release, crystalline salt formulation of diazoxide, which is administered once-daily. The parent molecule, diazoxide, as an oral suspension, has been used for decades in thousands of patients in a few rare diseases in neonates, children and/or adults, but not in PWS. Essentialis conceived of and established extensive patent protection on the therapeutic use of diazoxide and DCCR in patients with PWS. 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, as well as a pilot study in PWS patients. In the PWS pilot study, DCCR showed promise in addressing the hallmark symptoms of PWS, most notably hyperphagia.

About Soleno Therapeutics, Inc.

Soleno Therapeutics, Inc. (Soleno) is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company is currently advancing its lead candidate, DCCR, a once-daily oral tablet for the treatment of PWS, into a Phase III clinical development program at the end of 2017. Soleno, through its wholly owned subsidiary, Capnia, Inc., continues to market Capnia’s innovative medical devices, including the CoSense® End-Tidal Carbon Monoxide (ETCO) monitor, which measures ETCO and is used by hospitals to detect hemolysis in newborns, and the NeoForce portfolio of neonatal pulmonary resuscitation solutions. It is expected that these products will be monetized and will not be a focus for the company in the long term.

For more information, please visit www.soleno.life.

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 initiate the Phase III clinical development program of DCCR in PWS by the end 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 May 11, 2017, 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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Primary Logo

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