Soleno Therapeutics Announces Receipt of Scientific Advice from the European Medicines Agency for DCCR in Prader-Willi Syndrome

September 25, 2017

REDWOOD CITY, Calif., Sept. 25, 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 scientific advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) 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.

The EMA indicated that a single pivotal trial would support a Marketing Authorisation Application. They also indicated their general acceptance of several key aspects of the proposed development plan, on which general agreement had been reached previously with the U.S. Food and Drug Administration (FDA).

The EMA expressed their support for change in hyperphagia compared to placebo as the primary endpoint for the study. In addition, the dosing paradigm proposed by Soleno for the study was accepted, as it was during Soleno's scientific advice meeting with the FDA. The EMA also commented that Soleno could treat children with hyperphagia in the study without further toxicology work.

"We are encouraged by the constructive guidance we have received from both the FDA and EMA regarding the regulatory pathways for DCCR for the treatment of PWS," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. "We are pleased that the EMA agreed that a single Phase III study would form the basis of an MAA. Both the FDA and EMA have now stated that the use of change in hyperphagia score is an appropriate primary endpoint, a critical aspect of our development plan. We continue to believe that DCCR has the potential to be a safe and effective treatment for PWS patients, and look forward to initiating the Phase III program before the end of 2017."

About Scientific Advice

The EMA provides scientific advice to facilitate the development and availability of new safe and effective medicines for patients. This prospective advice focuses on development strategies, including the design of studies and other tests, to ensure that no major objections will be raised during the Marketing Authorisation Application (MAA) evaluation. The scientific advice provided by the EMA is not legally-binding; however, following the EMA's advice increases the probability of a positive outcome.

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.

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 is pursuing an extensive patent portfolio relating to various aspects of 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. DCCR has received Orphan Drug Designation from the US FDA for the treatment of PWS.

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. It is expected that CoSense 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 Soleno's Form 10-Q filed with the Securities and Exchange Commission on August 11, 2017, including under the caption titled "Risk Factors." Soleno expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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