Soleno Therapeutics Receives Positive Opinion from European Orphan Committee for DCCR in Prader-Willi Syndrome

October 12, 2017

REDWOOD CITY, Calif., Oct. 12, 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 the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion recommending Diazoxide Choline Controlled-Release Tablet (DCCR) for designation as an orphan medicinal product 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 COMP's positive opinion recommending DCCR's designation as an orphan drug provides further validation of its potential to treat PWS patients," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. "PWS patients have significant unmet needs for which there are currently no safe and effective treatment options available. We appreciate EMA's support for the development of DCCR, and look forward to commencing our Phase III program."

The COMP issues an opinion on the granting of orphan drug designation, after which the opinion is submitted to the European Commission (EC) for adoption. Orphan drug designation by the EC provides regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union (EU), and where no satisfactory treatment is available. In addition to a 10-year period of marketing exclusivity in the EU after product approval, orphan drug designation provides incentives for companies seeking protocol assistance from the EMA during the product development phase, and direct access to the centralized authorization procedure.

Soleno is currently finalizing the design of a randomized, double-blind, placebo-controlled Phase III study for DCCR that will treat approximately 100 PWS patients. This study is anticipated to take approximately 9-12 months to complete and is expected to be initiated at the end of 2017. DCCR previously received orphan designation for the treatment of PWS in the U.S.

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, in the absence of effective limitations to access to food, can lead to morbid obesity. 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. Soleno 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 five 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 device, 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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