Soleno Therapeutics Announces Successful End-of-Phase II Meeting with FDA for DCCR in Prader-Willi Syndrome

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Minutes Confirm Alignment on Soleno's Planned Phase III Clinical Trial

Soleno In Process of Initiating Phase III Study

REDWOOD CITY, Calif., Feb. 20, 2018 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (NASDAQ:SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced the successful completion of and receipt of minutes from its End-of-Phase 2 Meeting with the US Food and Drug Administration (FDA) concerning 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 minutes confirmed that the FDA and Soleno are aligned on all key aspects of the Company's planned Phase III clinical trial for DCCR, which will be initiated in the near future.

"Alignment with the FDA on our Phase III clinical trial design of DCCR in PWS allows us to confidently initiate this study," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. "If approved, we believe DCCR has the potential to be a safe and effective treatment for PWS, a rare and life-threatening disease with significant unmet needs."

In the fourth quarter of 2017, Soleno raised aggregate gross proceeds of approximately $15 million through a private placement of the company's common stock in order to conduct the planned Phase III trial of DCCR in PWS.

Diazoxide choline has Orphan Drug Designation for the treatment of PWS in the US and EU.

About PWS
The Prader-Willi Syndrome Association USA (PWSA (USA)) estimates that one in 12,000 to 15,000 people have PWS. The prevalence of PWS is similar across all geographies and ethnicities. 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. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the US and EU.

About Diazoxide Choline Controlled-Release Tablet
Diazoxide choline controlled-release tablet is a novel, proprietary extended-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, infants, children and/or adults, but not in PWS. Soleno 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 five completed Phase I clinical studies in various metabolic indications or in healthy volunteers and three completed Phase II clinical studies, one of which was in PWS patients. In the PWS Phase II study, DCCR showed promise in addressing the hallmark symptoms of PWS, most notably hyperphagia.

About Soleno Therapeutics, Inc.
Soleno Therapeutics, Inc. 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 in early 2018.

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 in early 2018.

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 press release 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 November 14, 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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