Soleno Therapeutics Receives Fast Track Designation from FDA for DCCR for Treatment of Prader-Willi Syndrome

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Phase III Clinical Trial Ongoing at Multiple Sites in the U.S.

REDWOOD CITY, Calif., July 30, 2018 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ:SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Diazoxide Choline Controlled-Release (DCCR) for the treatment of Prader-Willi Syndrome (PWS). Soleno is currently conducting a Phase III clinical trial of DCCR for the treatment of PWS.

Fast Track designation is intended to provide patients with serious conditions and unmet medical needs access to new drugs earlier by assisting their development and accelerating their review by the FDA. Fast Track designation allows additional meetings with the FDA to discuss Soleno's development plan to ensure the appropriate data are collected and encourages frequent written communication with the FDA regarding design of clinical trials and use of biomarkers. If certain criteria are met, the drug will be eligible for *Accelerated Approval and Priority Review* and also *Rolling Review*, which allows Soleno to submit to the FDA sections of its New Drug Application (NDA) as they are finished instead of waiting for all sections to be completed before submitting the marketing application.

"The receipt of Fast Track designation represents a significant milestone for Soleno and our DCCR clinical development program," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics, Inc. "PWS is a devastating condition with high unmet medical need and, based on the data generated to date, we believe DCCR has the potential to address this critical treatment gap. Enrollment in our Phase III clinical trial for DCCR in PWS is ongoing at multiple sites in the U.S. With Fast Track designation, we look forward to continued collaboration with the FDA, with the goal of delivering DCCR to patients in need as expeditiously as possible."

Diazoxide choline has orphan drug designation for the treatment of PWS in the U.S. and E.U.

About PWS
The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people in the U.S. have PWS. The hallmark symptom of this disorder is hyperphagia, a chronic feeling of insatiable hunger that severely diminishes the quality of life for PWS patients and their families. Additional characteristics of PWS include 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 (e.g., stomach rupture, obesity, diabetes, cardiovascular disease) and mortality (e.g., choking, accidental death due to food seeking behavior). In a global survey conducted by the Foundation for Prader-Willi Research, 96.5% of respondents (parent and caregivers) rated hyperphagia 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 Orphan Drug Designation for the treatment of PWS in the U.S. and E.U.

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, has been used for decades in thousands of patients in a few rare diseases in neonates, infants, children and adults, but has not been approved for use 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 trials in various metabolic indications or in healthy volunteers and three completed Phase II clinical trials, one of which was in PWS patients. In the PWS Phase II clinical trial, DCCR showed promise in addressing hyperphagia, as well as several other hallmark symptoms of PWS.

About Soleno Therapeutics, Inc.
Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Soleno's lead candidate, DCCR, a once-daily oral tablet for the treatment of PWS, is currently being evaluated in a Phase III clinical development program.

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 complete the Phase III clinical development program of DCCR in PWS in 2019.

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 May 15, 2018, 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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Source: Soleno Therapeutics