Soleno Therapeutics Presents Clinical Fat Loss Data on DCCR at the Obesity Society Meeting 2018

November 15, 2018

DCCR treatment resulted in statistically significant decreases in body fat in subjects with Prader-Willi Syndrome

REDWOOD CITY, Calif., Nov. 15, 2018 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (NASDAQ:SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that clinical data from a Phase II study (PC025) of diazoxide choline controlled release (DCCR) investigating the effects of DCCR treatment on hyperphagia and fat loss in patients with Prader-Willi Syndrome (PWS) were delivered today in a poster presentation at the Obesity Society Meeting 2018, taking place this week in Nashville, TN.

“While the hallmark characteristic of PWS is hyperphagia, PWS patients also experience ectopic accumulation of body fat, obesity and associated cardiometabolic complications, which is the leading cause of death of PWS patients,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. “The clinical data presented at the Obesity Society Meeting demonstrates that in addition to improving hyperphagia, treatment with DCCR also leads to statistically significant reductions in body fat in PWS patients. These data provide further clinical evidence that DCCR has the potential to treat both the behavioral and cardiometabolic symptoms that challenge PWS patients. We are encouraged by these significant impacts on body fat and continue to advance our ongoing DESTINY PWS Phase III trial.”

Jennifer Miller, M.D., Associate Professor in the Division of Pediatric Endocrinology at the University of Florida College of Medicine and senior author of the study said, “PWS is complex and challenging to treat as a neurobehavioral and metabolic disease. By addressing both hyperphagia and the underlying metabolic disease manifestations, DCCR has the potential to provide a treatment option for patients that will simplify disease management and improve quality of life, particularly as DCCR is suitable for once daily oral dosing. We look forward to the results of Soleno’s ongoing DESTINY PWS Phase III trial for DCCR.”

Neil Cowen, Ph.D., Senior Vice President of Drug Development, Soleno Therapeutics, presented the poster presentation titled, “Agonizing the K_{ATP} Channel with DCCR Results in Fat Loss in Prader-Willi Syndrome Patients.”

Presentation highlights:

- Patients who received 10 weeks of treatment with DCCR demonstrated statistically significant loss of total body fat mass, without additional caloric restrictions.
- Treatment with DCCR resulted in a statistically significant reduction in waist circumference, consistent with the loss of visceral fat.
- The 4.2mg/kg dose, the high dose in this Phase II study and the target dose in the ongoing DESTINY PWS Phase III trial, led to greater loss of body fat compared to lower doses, with the preferential loss of visceral and subcutaneous fat from the legs.

An electronic version Soleno Therapeutics’ poster presentation can be found on the Events & Presentations page of the Company’s Investor Relations website: http://investors.soleno.life/events-and-presentations/event-calendar.

About PWS
The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people in the US 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 received 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 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 hyperphagia, the hallmark symptom of PWS, as well as several other symptoms such as aggressive/destructive behaviors, fat mass and abnormal lipid profiles.

About Soleno Therapeutics, Inc.
Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company’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 annual and quarterly reports filed with the Securities and Exchange Commission, 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.

Corporate Contact:
Brian Ritchie
LifeSci Advisors, LLC
212-915-2578

Media Contact:
Allison Blum, Ph.D.
LifeSci Public Relations
646-627-8383

Source: Soleno Therapeutics