Soleno Therapeutics Announces Issuance of New U.S. Patent for DCCR Covering Treatment of Low Lean Body Mass in Prader-Willi Syndrome

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REDWOOD CITY, Calif., Sept. 04, 2018 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, announced today the issuance of a new patent (No. 10/058,557) from the U.S. Patent and Trademark Office related to the use of pharmaceutical formulations of diazoxide and diazoxide choline to increase lean body mass and the lean body mass/fat mass ratio in patients with Prader-Willi syndrome (PWS). PWS is a rare and complex genetic neurobehavioral and metabolic disorder affecting appetite, body composition, growth, metabolism, cognitive function, and behavior.

“This patent further strengthens Soleno’s intellectual property portfolio in the treatment of PWS,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “Low lean body mass is a significant challenge for PWS patients, impacting both physical activity and metabolism. We hope that treatment with DCCR will result in increases in lean body mass, and are currently evaluating this as an outcome measure in our ongoing Phase III trial.”

Low muscle mass, reflected in low lean body mass and weak muscles (hypotonia), are universal characteristics of PWS. Together, these limit the ability of PWS patients to carry out day-to-day activities and lead active lifestyles. Since PWS patients have lower muscle mass, they use less energy at rest and when active, and therefore need to consume fewer calories per day to meet their energy needs than do others. In Soleno’s Phase II study of DCCR in PWS patients, statistically significant improvements in lean body mass were observed.

Enrollment in Soleno’s Phase III clinical trial for DCCR in PWS has commenced at multiple sites in the U.S. The U.S. Food and Drug Administration has designated the investigation of DCCR for the treatment of PWS a Fast Track development program. In addition, Diazoxide choline has received orphan drug designations 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 mass and 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 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.

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