Soleno Therapeutics Presents Clinical Data on DCCR at 2018 Foundation for Prader-Willi Research Annual Conference

October 8, 2018

Oral presentation on DCCR's mechanism of action in treating hyperphagia

Poster presentation on DCCR's safety profile and implications for PWS Phase III study design

REDWOOD CITY, Calif., Oct. 08, 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 data supporting a potential mechanism of action paired with phase II data, and clinical safety data of diazoxide choline controlled release (DCCR), supporting the Phase III study design in Prader-Willi Syndrome (PWS), were presented in oral and poster presentations on October 4, 2018, at the 2018 Foundation for Prader-Willi Research Annual Conference (FPWR), in Las Vegas.

"The data presented on DCCR at this year's FPWR continue to support the design of our ongoing Phase 3 trial," said Anish Bhatnagar M.D., Chief Executive Officer of Soleno Therapeutics. "These results indicate that DCCR targets the underlying neural mechanisms of hyperphagia in PWS. Published preclinical and Phase II clinical data provide evidence-backed rationale for DCCR treating hyperphagia in this patient population. The safety and dosing findings from eight clinical studies of DCCR further demonstrate DCCR's well-established safety profile and the benefit of dose titration, which was utilized in our Phase II PWS study and is incorporated into our Phase III trial."

Neil Cowen, Ph.D., Senior Vice President of Drug Development, Soleno Therapeutics, delivered an oral presentation titled, "DCCR-mediated agonization of the ATP-sensitive potassium channel: A proposed mechanism of action to treat hyperphagia in PWS patients."

Presentation highlights:

- Neural mechanism underlying hyperphagia in PWS may be driven by excessive secretion of two neurotransmitters, NPY and AgRP, from NAG neurons of the hypothalamus, regulated by leptin and insulin through agonism of the K_{ATP} channel
- DCCR directly agonizes K_{ATP} channels in NAG Neurons, lowering NPY and AgRP secretion
- Directly agonizing K_{ATP} channels via diazoxide has demonstrated reductions of hyperphagia in multiple animal models of NPY-driven hyperphagia
- Consistent with this mode of action, reductions in hyperphagia were documented in a successfully completed Phase II clinical study of DCCR in PWS

Jennifer Abuzzahab, M.D., Children's Hospitals and Clinics of Minnesota, Department of Diabetes & Endocrinology, presented a poster entitled, "Safety Profile of DCCR and Implications for PWS Study Design."

Presentation highlights:

- DCCR's once-daily dosing demonstrates potential for increased safety over diazoxide
- Adverse events with DCCR are consistent with the known profile of diazoxide, with frequency and/or severity reduced with dose titration
- Dosing period of ≥ 10 days at each titration step effectively improved the safety profile
- Based on this dosing paradigm, which was also used in the PWS Phase II study, the ongoing Phase III trial includes titration steps lasting approximately two weeks each.

Electronic versions of both posters can be found on the Events & Presentations page of Soleno Therapeutics' 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.

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