Soleno Therapeutics Presents Clinical Data on DCCR at Late-Breaking Session of European Society for Paediatric Endocrinology

October 1, 2018

Pharmacokinetic data supports once-daily dosing
Long-term use of DCCR not associated with compromised glycemic control

REDWOOD CITY, Calif., Oct. 01, 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 pharmacokinetic and glycemic impact data from studies of Soleno's lead product candidate, diazoxide chloride controlled release (DCCR) for the treatment of Prader-Willi Syndrome (PWS), were presented as two posters during a late-breaking session on September 29, 2018, at the 57th Annual European Society for Paediatric Endocrinology (ESPE) Meeting in Athens, Greece.

"The pharmacokinetic data presented at ESPE clearly demonstrate that DCCR is suitable for once-daily dosing, which is important for patient compliance, particularly in children," said Anish Bhatnagar M.D., chief executive officer of Soleno Therapeutics. "In addition, DCCR's constant intraday circulating drug levels have the potential to reduce the likelihood of adverse events that can be associated with drug level fluctuations. We are also encouraged by the data from these studies demonstrating that treatment with DCCR is not associated with compromised glycemic control. As PWS is a complex metabolic disorder with significant morbidity and mortality resulting from obesity and diabetes, it is critical that long-term treatment with DCCR does not negatively impact glycemic control. Together, these data provide additional evidence supporting the continued development of DCCR, currently in a Phase III trial, as a treatment for PWS."

Parisa Salehi, M.D., Seattle Children's Hospital, Division of Endocrinology, University of Washington, presented a poster entitled, "Pharmacokinetics of Diazoxide Choline Controlled-Release Tablet, a Once Daily Treatment Being Evaluated for Patients with Prader Willi Syndrome."

Presentation highlights:

- Single-dose and steady state pharmacokinetics of DCCR were characterized across five studies
- DCCR consistent intraday dosing demonstrating suitability for once-a-day dosing
- Pharmacokinetic properties were consistent among multiple populations, including pediatric and adult PWS patients and obese non-PWS subjects

Virginia Kimonis, M.D., Division of Genetics and Metabolism, School of Medicine, University of California, Irvine, was the primary author on a poster entitled, "Glycemic Impact of Long Term Use of Diazoxide Choline Controlled-Release (DCCR) Tablets in Patients with Prader Willi Syndrome or with Very High Triglycerides."

Presentation highlights:

- Placebo-controlled data demonstrated that up to 18 weeks of treatment is not associated with compromised glycemic control for most individuals, despite short-term increases in glucose
- Impact on glycemic control was similar between groups, including obese, insulin-resistant patients with high triglycerides and PWS patients who are generally obese, but hypoinsulemic and insulin sensitive

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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