Soleno Therapeutics Announces Positive Outcome from Planned Data Safety Monitoring Board Review of Phase III DESTINY PWS Clinical Trial of DCCR in Prader-Willi Syndrome

March 14, 2019

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Mar. 14, 2019-- Soleno Therapeutics, Inc. (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that the Data Safety Monitoring Board (DSMB) has recommended the continuation of the Company's Phase III trial in Prader-Willi Syndrome (PWS) patients, DESTINY PWS, without any changes.

"We are delighted with the DSMB's positive recommendation to continue the Phase III trial as planned as it further supports DCCR's safety profile," said Dr. Anish Bhatnagar, Chief Executive Officer of Soleno. "We are continuing to enroll patients with 14 sites activated in DESTINY PWS. In addition, patients continue to roll over into C602, the 9-month open-label safety extension study for patients completing blinded treatment in the DESTINY PWS study."

The Phase III DESTINY PWS trial is a randomized, double-blind, placebo-controlled study of once daily oral administration of DCCR versus placebo in approximately 100 patients with a confirmed diagnosis of PWS. The primary endpoint is change from baseline hyperphagia score at Week 13. Patients who complete DESTINY PWS have the option to enroll into C602.

The DSMB is a group of independent experts monitoring the safety of the DESTINY PWS study. The DSMB reviews safety information and can make recommendations to either continue the study without modification, modify the study or terminate the study due to safety concerns.

In July 2018, the U.S. Food and Drug Administration designated the investigation of DCCR for the treatment of PWS to be a Fast Track development program. Prior to this, diazoxide choline received orphan designation for the treatment of PWS in the U.S. and in the E.U.

For further information about the trial (NCT03440814), please visit: www.clinicaltrials.gov.

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 data from five completed Phase I clinical studies 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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Source: Soleno Therapeutics, Inc.

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

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