Soleno Therapeutics Completes Target Enrollment in Ongoing DESTINY PWS Phase III Trial of DCCR in Prader Willi Syndrome

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Company Continues to Expect Top-line Data in First Half of 2020

REDWOOD CITY, Calif., Jan. 06, 2020 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (NASDAQ: SLNO, the Company or Soleno), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that it has completed its target enrollment of approximately 100 subjects in the ongoing Phase III trial, DESTINY PWS, evaluating once-daily Diazoxide Choline Controlled-Release (DCCR) tablets for patients with Prader-Willi Syndrome (PWS). Additional patients who are currently scheduled to be screened for DESTINY PWS will be enrolled over the next few weeks.

"The achievement of target enrollment represents an important milestone for our DESTINY PWS clinical program," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. "We remain on track to announce top-line data in the first half of 2020. Moreover, we continue to be encouraged by the significant interest shown by families and investigators in keeping patients on DCCR. On behalf of everyone at Soleno, I would like to extend my gratitude to all of the patients, families and investigators involved in this study, as well as the Foundation for Prader-Willi Research (FPWR) and Prader-Willi Syndrome Association (PWSA) USA and UK for their support of DESTINY PWS."

As of January 3, 2020, more than 95% of the patients randomized into DESTINY PWS have either completed or continue to be treated on study. More than 95% of patients enrolled in the C602 open-label extension study remain on treatment. Enrollment of patients was from 27 sites in the U.S. and the UK. No serious, unexpected adverse events related to DCCR have occurred in DESTINY PWS to date.

Based on the interest of the clinical investigators and families, Soleno will continue to make DCCR available to patients enrolled in the current program. The Company has, therefore, extended the C602 open-label extension study, allowing interested patients and families to continue in the study for up to two additional years.

DESTINY PWS 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. Patients who complete DESTINY PWS have the option to enroll into the C602 open-label extension study.

The U.S. Food and Drug Administration has designated the investigation of DCCR for the treatment of PWS to be a Fast Track development program. DCCR has also received orphan designation for the treatment of PWS in the U.S. and in the EU.

For further information about DESTINY PWS (NCT03440814) and C602 (NCT03714373), please visit: www.clinicaltrials.gov.

About PWS
The Prader-Willi Syndrome Association USA estimates that one in 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 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., and Fast Track Designation in the U.S.

About Diazoxide Choline Controlled-Release (DCCR) 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, Diazoxide Choline Controlled Release (DCCR) tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (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 within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding the Company's expectations concerning, among other things, our ability to receive top-line data in the first half of 2020 from Phase III DESTINY PWS. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar

expressions. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including the risks and uncertainties associated with market conditions, as well as risks and uncertainties inherent in Soleno's business, including those described in the company's prior press releases and in the periodic reports it files with the SEC. The events and circumstances reflected in the company's forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, the company does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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