Soleno Therapeutics Completes Enrollment in Randomized Withdrawal Period of Study C602 of DCCR for Prader-Willi Syndrome

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Top-line data expected in Q3 2023 and has the potential to support an NDA submission for DCCR in Prader Willi Syndrome

Enrollment completion satisfies closing condition on December 2022 Securities Purchase Agreement and triggers $10 million capital infusion

REDWOOD CITY, Calif., May 03, 2023 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (“Soleno”) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that it has completed enrollment in the randomized withdrawal period of Study C602, a long-term treatment study of DCCR (Diazoxide Choline) Extended-Release tablets for the treatment of Prader-Willi syndrome (PWS). The U.S. Food and Drug Administration (FDA) previously acknowledged that data from the study has the potential to support a New Drug Application (NDA) submission for DCCR.

“We are pleased that enrollment in the randomized withdrawal period of Study C602 is now complete,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “We would like to thank the participants, their families and the study sites for helping us reach this significant milestone for our late-stage DCCR program. Furthermore, it enables the Company to receive $10 million under the Securities Purchase Agreement executed in December 2022, which will support clinical operations through top-line data leading to a potential NDA filing and approval of DCCR. We continue to expect top-line results in the third quarter of 2023.”

The randomized withdrawal period of Study C602 is a multi-center, randomized, double-blind, placebo-controlled study of DCCR that enrolled 77 patients with PWS at 17 sites in the U.S. and 5 sites in the U.K. The randomized withdrawal period consists only of patients previously enrolled in Study C602, with 93% of the total 83 patients participating, which was inline with expectations. Participants were randomized to receive either DCCR or placebo for a period of four months.

Soleno entered into a Securities Purchase Agreement with Nantahala Capital Management, LLC, Abingworth LLP and Vivo Capital, LLC in December 2022, which may result in gross proceeds to the Company of up to $60 million (the Securities Purchase Agreement). Under the terms of the Securities Purchase Agreement, the investors committed to pay $10 million in exchange for warrants to purchase common stock upon the Company’s announcement of enrollment completion in the randomized withdrawal period of Study C602.

About PWS
The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births in the U.S. 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., obesity, diabetes, cardiovascular disease) and mortality (e.g., stomach rupture, 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 and 92.9% rated body composition as either 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 DCCR (Diazoxide Choline) Extended-Release Tablets
DCCR is a novel, proprietary extended-release dosage form containing the crystalline salt of diazoxide and 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 1 clinical studies in healthy volunteers and three completed Phase 2 clinical studies, one of which was in PWS patients. In the PWS Phase 3 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 other metabolic parameters.

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 extended-release tablets, a once-daily oral tablet for the treatment of PWS, is currently being evaluated in a Phase 3 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 closing of the warrant financing under the Securities Purchase Agreement, the receipt of top-line data from the randomized withdrawal period, and the timing of any regulatory process or ultimate approvals and determining a path forward for DCCR for the treatment of 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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