



Soleno Therapeutics Provides Regulatory Update on DCCR for the Treatment of Prader-Willi Syndrome

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FDA acknowledges that data from a randomized withdrawal period of Study C602 have the potential to support an NDA submission

REDWOOD CITY, Calif., July 20, 2022 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno or the Company) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today provided an update following recent communications with the U.S. Food and Drug Administration (FDA) regarding the development of once-daily DCCR (diazoxide choline) extended-release tablets for the treatment of Prader-Willi syndrome (PWS).

Following a recent meeting, the FDA acknowledged that data from a proposed randomized withdrawal phase of Study C602 would have the potential to address its concerns regarding the adequacy of the overall efficacy data supportive of a New Drug Application (NDA) submission for DCCR. Earlier this year, Soleno submitted a proposal to add a randomized withdrawal period to Study C602 in order to obtain additional controlled data requested by the FDA to support an NDA. This randomized withdrawal phase would consist only of participants currently enrolled in Study C602 and not include any new patients. The Company continues to work collaboratively with the FDA to finalize specific details of the study design and plans to initiate the randomized withdrawal period in the current quarter, with top-line data expected in the first quarter of 2023.

"We are pleased to continue our constructive dialogue with the FDA. This randomized withdrawal period may enable us to obtain the data needed to support an NDA in an efficient and timely manner," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We appreciate the continued support of the participants and families in Study C602 in helping move the DCCR development program forward."

Study C602 is an open-label extension study comprised of patients who completed DESTINY PWS, an international, multi-center, randomized, double-blind, placebo-controlled study of DCCR. The Protocol for C602 has been amended to include a randomized withdrawal period.

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 % body composition 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 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 Prader-Willi syndrome (PWS), is currently being evaluated in a Phase 3 clinical development program. For more information, please visit www.solenolife.com.

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 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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