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

July 6, 2021

FDA agrees to review additional data to determine adequacy for submission of NDA

REDWOOD CITY, Calif., July 06, 2021 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (“Soleno”) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today provided an update following a recent interaction 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).

On July 2, 2021, the Company received official meeting minutes from the June 11th, 2021, Type B meeting with the Division of Diabetes, Lipids and Obesity. Included in the meeting was the “patient voice” represented by the PWS advocacy organizations, as well as the family of a DCCR trial participant. The FDA continued to assert that based on the data they have seen to date, an additional clinical trial is necessary for the submission of a New Drug Application (NDA). However, the FDA strongly encouraged Soleno to submit the available data and clinical study reports for the Company’s Phase 3 trial, DESTINY PWS (C601), and its long-term, open-label extension study (C602) to allow them to assess if these studies may provide adequate evidence of safety and efficacy to support the submission of an NDA.

“We are continuing our dialogue with the FDA and remain focused on our goal of achieving approval for DCCR for the treatment of PWS,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “We appreciate the opportunity to include the patient voice in our discussions with the Division. We intend to submit additional data from DESTINY PWS and the C602 extension study to the Agency before the end of the third quarter. The FDA has agreed to review these data to determine if the totality of data generated to date are sufficient to support a potential NDA submission.”

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 EU, 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.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 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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