



Correcting & Replacing -- Soleno Therapeutics Announces DCCR Data Presentation at the Foundation for Prader-Willi Research Symposium

October 4, 2023 10:16 PM EDT

In a press release issued earlier this afternoon, the time zone of the FPWR Research Symposium presentation was labeled as Central Time. The correct time zone is Mountain Time.

The corrected press release is posted below.

REDWOOD CITY, Calif., Oct. 04, 2023 (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 announced an oral presentation at the Foundation for Prader-Willi Research (FPWR) 2023 Research Symposium, being held October 5-6, 2023, in Denver, Colorado. The presentation features results from the recently completed 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).

Presentation details can be found below:

FPWR 2023 Research Symposium

Title: Rationale for and Results from a Randomized Withdrawal Period Following Long-Term Administration of Diazoxide Choline Extended-Release Tablets to People with Prader-Willi Syndrome
Presenter: Jennifer L. Miller, M.D. (University of Florida)
Format: Oral Presentation
Date/Time: Thursday, October 5, 2023 at 2:00 – 2:20 PM MDT
Location: Westin, Downtown Denver
Livestream: [Click Here](#)

About PWS

The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The hallmark symptom of this disorder is hyperphagia, a chronic and life-threatening feeling of intense, persistent hunger, food pre-occupation, extreme drive to food seek and consume food that severely diminish the quality of life for patients with PWS 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.

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, diazoxide choline 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 patients with PWS. In the PWS Phase 3 clinical development program, 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. 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 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, recently completed its Phase 3 development program to support a planned NDA submission. 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 potential receipt of gross proceeds from the warrant financing under the Securities Purchase Agreement, management's assessment of the top-line data results from the randomized withdrawal period, and the timing and pathway of the regulatory process and clinical development path for seeking approval of 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," "goal," "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 U.S. Securities and Exchange Commission. 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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Source: Soleno Therapeutics