Soleno Therapeutics Receives Breakthrough Therapy Designation from U.S. FDA for DCCR (Diazoxide Choline) Extended-Release Tablets in Prader-Willi Syndrome (PWS)

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First Ever Breakthrough Designation for a Drug Being Developed for PWS

Designation is Based on Data from the Phase 3 Program for DCCR

Planned Submission of a New Drug Application (NDA) for DCCR Remains on Track for Mid-2024

REDWOOD CITY, Calif., April 29, 2024 (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 the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to diazoxide choline for the treatment of adults and children ages 4 years and older with genetically confirmed Prader-Willi syndrome (PWS) who have hyperphagia. The designation reflects the Agency's determination that, based on an assessment of the preliminary data from the Phase 3 clinical development program, diazoxide choline may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies.

"The granting of Breakthrough Therapy Designation, the first for a drug being developed for the treatment of PWS, marks another important milestone for our DCCR clinical development program," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "This important designation is confirmation that the FDA views PWS as a serious condition and is an indication of DCCR's potential to be a safe and effective treatment for PWS. We remain focused on preparing our NDA submission for DCCR in PWS, which we continue to expect will occur in mid-2024."

The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of drugs in the U.S. that are intended to treat a serious condition, when preliminary clinical evidence indicates the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). With Breakthrough Therapy Designation, FDA provides intensive guidance and organizational commitment involving senior managers in a proactive, collaborative, cross-disciplinary review, and may also allow for priority review and other actions to expedite review.

Diazoxide choline has Orphan Drug Designation for PWS in the U.S. and E.U., as well as Fast Track Designation in the U.S.

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 diazoxide choline, the crystalline salt of diazoxide, and is administered once-daily. Soleno conceived of and established extensive patent protection for 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 and Breakthrough Designations 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, recently completed its Phase 3 development program in patients with PWS 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 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 the projected timeline of our NDA submission, whether FDA will agree with our interpretation of the data or the adequacy of data to support an NDA, the FDA's review of our NDA, 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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