Soleno Therapeutics Announces Presentation of Long-Term Hyperphagia and Behavioral Data in Patients Receiving DCCR for Treatment of Prader-Willi Syndrome

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Results Show Significant Improvements in Hyperphagia and PWS-Related Behaviors in DCCR-Treated Patients

Presentations at the Pediatric Academic Societies 2022 Virtual Annual Meeting and Pediatric Endocrinology Society 2022 Virtual Annual Meeting

REDWOOD CITY, Calif., May 02, 2022 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. ("Soleno") (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced two presentations highlighting the results from a study evaluating diazoxide choline extended-release (DCCR) tablets under development for the treatment of Prader-Willi Syndrome (PWS) in patients who completed its DESTINY PWS study and then continued into the open-label extension clinical study (C601/C602). The data were presented by Theresa Strong, Ph.D., Director of Research Programs, Foundation for Prader-Willi Research (FPWR), at the Pediatric Academic Societies 2022 Virtual Annual Meeting, and Jennifer Miller, M.D., Professor in the Division of Pediatric Endocrinology for the University of Florida Department of Pediatrics, at the Pediatric Endocrinology Society 2022 Virtual Annual Meeting.

Key highlights from the poster presentation, titled, *"Comparison of hyperphagia and behavioral features in Prader-Willi Syndrome (PWS) patients receiving Diazoxide Choline Extended-Release (DCCR) with matched participants in PATH for PWS Study (PfPWS NHS),"* presented by Dr. Strong were:

- Highly statistically significant reductions in HQ-CT total score for C601/C602 compared to the matched PfPWS cohort at Week 26 for propensity-adjusted and non-propensity-adjusted analyses and were sustained at Week 52 (all p<0.001)
    - Reduction of HQ-CT total score between the two cohorts was consistent across age, baseline HQ-CT, PWS subtype, region subgroups or growth hormone use
- Reduction of PWS Profile questionnaire scores for C601/C602 were statistically significant across all domains (aggression, anxiety, rigidity/irritability, compulsivity, depression, disordered thinking) in comparison to PfPWS NHS (p<0.001 for all) at Week 26 and maintained at Week 52 (p<0.001 to 0.003)

"We believe that these encouraging results show a long term, beneficial effect of DCCR on hyperphagia and other behaviors in patients with PWS when compared with the natural history of the disease," said Dr. Strong. "These results demonstrate that DCCR may be an effective treatment option for individuals with PWS, where behavioral abnormalities are very difficult to treat. FPWR continues to be encouraged by DCCR's potential to provide meaningful improvement to patients living with PWS and we look forward to continuing to support Soleno through the regulatory process."

Key highlights from the presentation, titled, *"An open-label, long-term safety and efficacy evaluation of diazoxide choline extended-release (DCCR) tablet in participants with Prader-Willi Syndrome,"* presented by Dr. Miller were:

- Highly statistically significant reductions from before DCCR treatment (baseline) in HQ-CT total score for C601/C602, as well as in the aggression, anxiety, compulsivity, depression, disordered thinking, and rigidity domains of the PWS Profile questionnaire at Week 52 (all p<0.0001)
- Statistically significant increase from baseline in lean body mass from baseline at Week 52 (p<0.0001) and an improvement of the ratio of lean body mass to fat mass (p=0.0005)
- Statistically significant improvements from baseline in metabolic and hormonal markers, including leptin, adiponectin (p ≤ 0.0001), and fasting insulin (p=0.0004) at Week 52
- Statistically significant improvement in insulin resistance from baseline (p=0.0033) as measured by HOMA-IR at Week 52
- Safety profile remains consistent with prior experience with DCCR

Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics, said, "These important data add to the growing body of evidence showing the long-term benefits of DCCR in patients with PWS, affirming our confidence in DCCR as a potential treatment for patients with PWS. The collective results were previously submitted to the U.S. Food and Drug Administration (FDA) as part of ongoing discussions regarding the clinical data needed to support a potential New Drug Application (NDA) for DCCR in PWS, and we look forward to continued discussions with the FDA."

The posters are available in the Presentations section of Soleno's website.

About DESTINY PWS/C601 and C602

These presentations included data from subjects who took part in a multi-center study conducted at 29 sites in the U.S. and the UK: a 13-week Phase 3 double-blind, placebo-controlled study (DESTINY PWS/C601) and its long-term, open-label extension study (C602) (through 52 weeks).

About PATH for PWS (PfPWS)

PATH from PWS (PfPWS) is an ongoing study sponsored by the Foundation for Prader-Willi Research (FPWR) to advance the understanding of the natural history in individuals with PWS.

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. Soleno has been in ongoing discussions with the FDA regarding additional data needed to support the submission of an NDA.

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, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in an ongoing 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.

Corporate Contact:
Brian Ritchie
LifeSci Advisors, LLC
212-915-2578

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