Soleno Therapeutics Announces Presentation of Positive Behavioral Data from Ongoing Extension Study of DCCR for Treatment of Prader-Willi Syndrome

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Results Show Improvement in Multiple Behavioral Domains Following Treatment with DCCR

Data Presented in a Poster at the Pediatric Academic Societies Annual Meeting

REDWOOD CITY, Calif., May 04, 2021 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. ("Soleno") (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced the presentation of positive behavioral outcomes data from the Company's ongoing open-label extension study (C602) of DCCR (diazoxide choline) Extended-Release tablets for patients with Prader-Willi Syndrome (PWS), at the Pediatric Academic Societies (PAS) 2021 Virtual Annual Meeting. The poster is available here.

As part of the ongoing Phase 3 program of DCCR in PWS, interviews are being conducted with caregivers of C602 study participants to characterize individual patient experiences with DCCR. The interviews are performed at multiple timepoints during the Phase 3 program by Casimir Inc., a rare disease research organization. The poster highlights the analysis of a subset of 48 interviews of caregivers whose child had received at least 13 weeks of DCCR treatment in C602. Folia Health, which utilizes a data driven platform to improve the treatment of chronic conditions, utilized a combination of natural language processing (NLP) and qualitative analytic techniques to process and analyze the transcript data from the caregiver interviews.

Through the 48 interviews, 39 behavioral outcomes were identified in seven outcome domains, with an average of 22±5.9 behaviors reported. The three most frequently reported domains were Food-seeking Behaviors (100%), Mealtime Behaviors (98%), and Daily Life Behaviors (98%). Twenty three percent of participants reported a negative behavior change and 6% reported more than one negative change. Most participants (83%) reported positive change in one or more behavioral outcomes on DCCR, more than 70% reported positive changes in one quarter or more of behaviors, while 48% reported positive changes in more than half of behaviors.

"It is exciting to see the utilization of natural language processing for the first time to determine caregiver sentiment in patients with PWS. NLP and other artificial intelligence techniques are the future of qualitative data analysis and can be particularly useful in rare-disease research. To my knowledge, this is the first report of the use of such techniques to understand the complex world of PWS outcomes," said Deepan Singh, M.D., Vice Chair of Ambulatory Psychiatry, Maimonides Medical Center in Brooklyn, NY. "Behavioral abnormalities in PWS are heterogenous and very difficult to treat. I am encouraged by DCCR's potential to impact these intractable problematic behaviors in individuals with PWS."

"These important data provide critical insights into the long-term behavioral responses to DCCR in PWS, and support a more complete view of this promising investigational drug's therapeutic benefits," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "The growing body of clinical evidence continues to indicate that DCCR has the potential to address the significant need for a safe and effective treatment for individuals with PWS. We remain firmly committed to working with the U.S. Food and Drug Administration to define the path forward for DCCR."

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 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.

About Casimir Inc.
Casimir is a Contract Research Organization (CRO) that develops novel outcomes for decentralized and hybrid trials in order to better understand disease progression and treatment benefit. Casimir works with sponsors in over 20 rare diseases in every facet of clinical services from preclinical development to Phase IV and siteless studies.

About Folia Health
Folia is a patient-driven Health-IOS (Individual Operating System) that enables individuals to easily take an active role in their care, while contributing to precision diagnostics, patient-centered drug development, & better care for complex diseases. Folia's rich longitudinal data and proprietary analytic methods provide a vital and missing piece in the emergence of a home-centered, data-driven healthcare ecosystem. Discover how to harness the power of patient and caregiver knowledge at www.foliahealth.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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