Soleno Therapeutics Presents Long Term Data for DCCR Showing Metabolic and Body Composition Improvements in Patients with PWS

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Patients demonstrated statistically significant improvements in several hormonal and cardiometabolic parameters following treatment with DCCR

REDWOOD CITY, Calif., June 13, 2022 (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 presented new positive clinical data from its ongoing late-stage DCCR development program for the treatment of Prader-Willi syndrome (PWS) at ENDO 2022, which is being held June 11-14, 2022, in Atlanta, Georgia, USA.

An oral presentation titled, “Hormonal and Cardiometabolic Changes Associated with Diazoxide Choline Extended-Release (DCCR) Tablets in Patients with Prader-Willi Syndrome,” presented by Dr. Eric Felner, Emory University School of Medicine, summarized data demonstrating positive hormonal, cardiometabolic and body composition changes in PWS patients following one year of treatment with DCCR. The patients were treated in C601, a Phase 3 randomized, double-blind, placebo-controlled study and C602, its ongoing open-label extension.

Patients (n=82) experienced improvements in body composition, as evidenced by statistically significant changes in lean body mass ($p<0.0001$) and the ratio of lean body mass to fat mass ($p=0.0005$), based on DXA scanning. These changes were accompanied by reduced levels of leptin ($p<0.0001$), fasting insulin ($p=0.0004$) and an improvement in insulin sensitivity (HOMA IR $p=0.0033$), likely related to a combination of reduced fat mass and improved leptin resistance. A statistically significant increase of adiponectin ($p<0.0001$), a cardioprotective marker, was also observed. Similar effects were observed in obese participants (n=40) enrolled in these studies.

“These important results show that the benefits of DCCR also extend to positive changes in objective metabolic parameters, in addition to prior data demonstrating improvements in hyperphagia and behavioral symptoms of PWS,” said Dr. Felner, a Principal Investigator of the DCCR C601/602 study. “These results further emphasize the potential for DCCR to be a meaningful treatment that improves multiple key symptoms of PWS, which has significant implications for patients and families struggling to manage this devastating disease.”

In addition a poster, titled, “Long-Term Safety of Diazoxide Choline Extended-Release (DCCR) Tablets in Patients with Prader-Willi Syndrome,” presented by Dr. Michael Woloschak, Vice President, Clinical Development, Soleno Therapeutics, highlighted the ongoing safety of DCCR, with the most common adverse events (hypertrichosis, hyperglycaemia, and peripheral edema) being as expected based on prior experience with DCCR.

A copy of this poster is available in the Investors section on the Company’s website at www.soleno.life

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 E.U., 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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