Soleno Therapeutics Announces Publication Evaluating Potential Role of Activating ATP-Sensitive Potassium Channel in Treatment of Hyperphagic Obesity

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Paper Published in Peer-Reviewed Journal, Genes, as Part of Special Supplement on Genetics of Prader-Willi Syndrome (PWS)

DCCR is the first K-ATP Channel activator being developed for PWS

Company expects to report top-line data from Phase III trial evaluating DCCR for PWS patients in Q2 2020

REDWOOD CITY, Calif., April 23, 2020 (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 a paper authored by Soleno's researchers entitled, "*The Potential Role of Activating the ATP-Sensitive Potassium Channel in the Treatment of Hyperphagic Obesity*," was published in the April edition of *Genes*, an open-access journal of genetics and genomics. The article is included in the journal's special supplement on the genetics of Prader-Willi Syndrome (PWS), and can be accessed here: https://www.mdpi.com/2073-4425/11/4/450/htm.

The ATP-sensitive potassium (K_{ATP}) channel is present in tissues that are critical to appetite regulation, and agonizing the channel is one of the primary mechanisms by which the hormones that regulate appetite, leptin, insulin and α-melanocortin stimulating hormone, exert their effects. Agonizing the channel in hyperphagic obesity results in a range of therapeutically relevant responses, including reducing appetite, improving satiety, reducing fat mass, decreasing circulating and liver fat, and improving insulin sensitivity.

The publication illustrates that these responses have been observed in numerous animal models of hyperphagic obesity. These responses have also been seen in diazoxide chloride-controlled release (DCCR)-treated patients with PWS, a rare genetic form of hyperphagic obesity. DCCR is the first K_{ATP} channel agonist being developed for the treatment of PWS.

"Treatment with DCCR can directly open the K_{ATP} channels in the NPY/AgRP neurons, which control appetite and energy expenditure, reducing the synthesis and secretion of NPY and AgRP, and thereby, reducing hyperphagia, the hallmark symptom of PWS. In addition, reduced secretion of insulin and improved insulin sensitivity may result in a variety of metabolic effects beneficial to PWS patients," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We have completed enrollment in our ongoing Phase III clinical trial, DESTINY PWS, evaluating DCCR in PWS patients, and remain on track to announce top-line data during the current quarter."

The U.S. Food and Drug Administration has designated the investigation of DCCR for the treatment of PWS to be a Fast Track development program. DCCR has also received orphan designation for the treatment of PWS in the U.S. and in the EU.

About PWS
The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people in the U.S. have PWS. 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., stomach rupture, obesity, diabetes, cardiovascular disease) and mortality (e.g., 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 E.U., and Fast Track Designation in the U.S.

About DESTINY PWS
DESTINY PWS is a randomized, double-blind, placebo-controlled study of once-daily oral administration of DCCR versus placebo in 127 randomized subjects. Patients who complete DESTINY PWS have the option to enroll into an open-label extension study (C602) and continue treatment with DCCR.

For further information about DESTINY PWS (NCT03440814), please visit: www.clinicaltrials.gov.

About Diazoxide Choline Controlled-Release (DCCR) Tablet
Diazoxide Choline Controlled-Release tablet is a novel, proprietary extended-release, crystalline salt formulation of diazoxide, which 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 I clinical studies in healthy volunteers and three completed Phase II clinical studies, one of which was in PWS patients. In the PWS Phase II 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 abnormal lipid profiles.

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, Diazoxide Choline Controlled-Release (DCCR) tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in a Phase III 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 the Company's expectations concerning, among other things, our ability to receive top-line data in the first half of 2020 from Phase III DESTINY 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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