Soleno Therapeutics Provides Recap of Key Opinion Leader Webinar on DCCR for Treatment of Prader-Willi Syndrome

February 5, 2021

Recent analysis of Phase 3 DESTINY PWS limited to data collected before the onset of the COVID-19 pandemic shows statistical significance in the primary and key secondary endpoints

REDWOOD CITY, Calif., Feb. 05, 2021 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. ("Soleno") (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today hosted a Key Opinion Leader (KOL) webinar and provided an update on the Company's ongoing Phase 3 program evaluating once-daily Diazoxide Choline Controlled Release (DCCR) tablets for the treatment of Prader-Willi Syndrome (PWS).

"PWS is estimated to impact about 10,000 – 20,000 people in the U.S., and is characterized by hyperphagia, an insatiable feeling of hunger, and various other behavioral and metabolic abnormalities that severely impact the daily lives of patients and their families," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Given the considerable impact of the COVID-19 pandemic, particularly for individuals with PWS and their families as highlighted during our webinar, it was critical for us to evaluate the data from our Phase 3 DCCR trial that was generated prior to the significant disruptions caused by the pandemic."

"Our analysis of the data through March 1, 2020 found statistically significant differences between DCCR and placebo patients for the primary and all key secondary endpoints. We continue to be encouraged by these data and positive changes experienced by our subjects with DCCR treatment. We look forward to continuing our interactions with the regulatory authorities," concluded Dr. Bhatnagar.

In an analysis of study results with data through March 1, 2020, a date shortly before a national emergency was declared due to COVID-19, the primary endpoint demonstrated a statistically significant change from baseline in hyperphagia for DCCR compared to placebo. The change was measured by the total score of a Hyperphagia Questionnaire for Clinical Trials (HQ-CT, 0-36). An improvement in HQ-CT is represented by a decrease in the score. Key secondary endpoints, as well as several additional subjective endpoints measuring improvement in behavior and communication, that were not significant in the top-line analyses, were also all significant in the analysis of data through March 1, 2020. No significant differences in safety were noted compared to the top-line analysis.

Analysis of Primary Endpoint

	Top-line analysis June 2020		**Data through March 1, 2020**	
	DCCR (N=82)	Placebo (N=42)	DCCR (N=80)	Placebo (N=41)
Change from Baseline in Hyperphagia	-5.94 (0.88)	-4.27 (1.15)	-6.64 (1.00)	-3.51 (1.28)
LS Mean Difference [DCCR-Placebo]	-1.67		-3.13	
p-value	**0.198**		**0.037**	

Key Secondary Endpoints

	Top-line analysis June 2020 p-value	**Data through March 1, 2020 p-value**
Clinical Global Impression of Improvement (CGI-I) at Visit 7	0.03	0.015
Change from Baseline in Body Fat Mass (DXA) at Visit 7	0.03	0.004
Caregiver Global Impression of Change (Caregiver GI-C) at Visit 7	0.41	0.031

In addition to the pre-COVID-19 data presented by Soleno at the webinar, Theresa Strong, Ph.D., co-founder and Director of Research Programs at the Foundation for Prader-Willi Research, provided an overview of the impact of the COVID-19 pandemic on more than 300 PWS patients and their families. Results from the Global PWS Registry's "Impact of COVID" Survey emphasized that PWS patients and their caregivers have experienced significant disruptions due to the COVID-19 pandemic. A significant proportion of caregivers (85%) reported more stress. For patients, lack of social activity, remote learning and the loss of in-person therapy have had a substantial negative impact, with the loss of routine and structure contributing to increased challenges in food control and behavioral management.

Jennifer Miller, M.D., Director of the University of Florida Health Prader-Willi Syndrome Program and a Professor in the Division of Pediatric Endocrinology at the UF Department of Pediatrics, provided a summary of PWS and the obstacles faced by PWS patients and their families. Dr. Miller also reviewed the current treatment landscape and unmet need in PWS, as well as the positive biochemical, physical, and behavioral changes observed to date with DCCR treatment in her patients.

A replay of the event is available in the Investors section on the Company's website at www.soleno.life.

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 1 clinical studies in healthy volunteers and three completed Phase 2 clinical studies, one of which was in PWS patients. In the PWS Phase 2 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. 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 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 results of clinical trials, 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 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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