Soleno Therapeutics Announces U.S. FDA Approval of VYKAT™ XR to Treat Hyperphagia in Prader-Willi Syndrome

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First approved therapy to address hyperphagia in individuals with Prader-Willi syndrome

Management to host conference call and webcast today, March 26th, at 5:30pm ET

REDWOOD CITY, Calif., March 26, 2025 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved VYKAT XR (diazoxide choline) extended-release tablets, previously referred to as DCCR, for the treatment of hyperphagia in adults and children 4 years of age and older with Prader-Willi syndrome (PWS). Soleno expects VYKAT XR to be available in the U.S. beginning in April 2025.

“The approval of VYKAT XR is a significant milestone for Soleno and, most importantly, for the PWS community who have had no options to treat the most disruptive aspect of this disease,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. “We are deeply grateful to the many individuals with PWS, their caregivers and clinical sites who participated in our trials, the advocacy groups, including FPWR and PWSA | USA, the advocates who have tirelessly supported the approval of VYKAT XR, the FDA for a collaborative review process, and our employees who have been committed to delivering VYKAT XR to those with PWS.”

“The FDA approval of VYKAT XR is an incredible achievement for the entire PWS community,” said Jennifer Miller, M.D., Professor of Pediatric Endocrinology at the University of Florida, Gainesville, who specializes in treating children and adults with PWS and is a principal investigator in the VYKAT XR clinical development program. “I am excited to have VYKAT XR available to help treat hyperphagia, which is the most life-limiting aspect of PWS. Families of people with PWS have been prisoners in their own homes because of the need to provide constant, eyes-on supervision 24/7 with access to food being completely restricted.”

“Today marks a historic day for the PWS community. The FDA’s approval of VYKAT XR represents a monumental step forward in addressing the longstanding unmet needs of individuals living with PWS and their families,” said Stacy Ward, Chief Executive Officer of the Prader-Willi Syndrome Association | USA. “Our families experience the constant and disruptive challenges of hyperphagia, and VYKAT XR offers hope to so many.”

"This approval is a testament to the power of persistence, science, and advocacy," said Susan Hedstrom, Executive Director of the Foundation for Prader-Willi Research. "For years, families and researchers have worked towards a treatment option that truly addresses the complexities of PWS. Today, we take a major step forward in changing the future for individuals navigating hyperphagia associated with PWS."

The FDA approval of VYKAT XR was based on an adequate and well-controlled study and safety data from the comprehensive clinical development program. Efficacy was established during the 16-week randomized withdrawal study period of Study 2-RWP (Study C602-RWP), a Phase 3 multi-center, randomized, double-blind, placebo-controlled trial. Individuals randomized to switch to placebo demonstrated a statistically significant worsening of hyperphagia compared with individuals who remained on VYKAT XR. Prior to participating in the randomized withdrawal period, all individuals received double-blind and/or open-label VYKAT XR for a mean duration of 3.3 years.

VYKAT XR has a well-established safety profile with over four years of data across four double-blind and/or open label studies. The primary safety analyses are based on Study 1 (Study C601) and the most common adverse reactions occurring in greater than or equal to 10% of individuals receiving VYKAT XR and at 2% greater than placebo included hypertrichosis, edema, hyperglycemia and rash.

Patient Support for Accessing VYKAT XR

Today, Soleno has launched ***Soleno One™***, a comprehensive patient support program. Information about the program is available at **VykatXR.com**. **The Soleno One team can be reached toll-free at 1-(833)-SOLENO-1 (1-833-765-3661) from 8 a.m. to 8 p.m. ET Monday through Friday.** Healthcare providers who want to submit prescriptions can visit **VykatXRHCP.com** to complete the Start Form that initiates the process for accessing treatment.

Conference Call and Webcast Information

Soleno management will host an investor conference call and webcast with slides to discuss the FDA’s approval of VYKAT XR (diazoxide choline) extended-release tablets today, March 26th, at 5.30pm ET. Details can be found below:

Conference call details:	Toll-free: 1-877-423-9813 International: 1-201-689-8573 Conference ID: 13752679
Call me™ (avoids waiting for an operator):	Click here
Webcast:	Click here

A replay of the call will be available following the call on the Investors section of the Soleno website.

About Prader-Willi Syndrome

Prader-Willi syndrome (PWS) is a rare genetic neurodevelopmental disorder caused by an abnormality in the gene expression on chromosome 15. The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The defining symptom of PWS is hyperphagia, a chronic and life-threatening condition characterized by an intense persistent sensation of hunger accompanied by food preoccupations, an extreme drive to consume food, food-related behavior problems, and a lack of normal satiety, which can severely diminish the quality of life for individuals with PWS and their families. Hyperphagia can lead to significant mortality (e.g., stomach rupture, choking, accidental death due to food seeking behavior) and longer term, co-morbidities such as diabetes, obesity, and cardiovascular disease.

INDICATION
VYKAT XR is indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).

IMPORTANT SAFETY INFORMATION

Contraindications
Use of VYKAT XR is contraindicated in patients who have a known hypersensitivity to diazoxide, other components of VYKAT XR, or to thiazides.

Warnings and Precautions

Hyperglycemia
Hyperglycemia, including diabetic ketoacidosis, has been reported. Before initiating VYKAT XR, test fasting plasma glucose (FPG) and HbA1c; optimize blood glucose in patients who have hyperglycemia. During treatment, regularly monitor fasting glucose (FPG or fasting blood glucose) and HbA1c. Monitor fasting glucose more frequently during the first few weeks of treatment in patients with risk factors for hyperglycemia.

Risk of Fluid Overload
Edema, including severe reactions associated with fluid overload, has been reported. Monitor for signs or symptoms of edema or fluid overload. VYKAT XR has not been studied in patients with compromised cardiac reserve and should be used with caution in these patients.

Adverse Reactions
The most common adverse reactions (incidence ≥10% and at least 2% greater than placebo) included hypertrichosis, edema, hyperglycemia, and rash.

Please see the full Prescribing Information, including Medication Guide**.**

About Soleno Therapeutics, Inc.
Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company's first commercial product, VYKAT XR (diazoxide choline) extended-release tablets, formerly known as DCCR, is a once-daily oral treatment for hyperphagia in adults and children 4 years of age and older with Prader-Willi syndrome. 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 timing of commercialization of VYKAT XR for the treatment of hyperphagia in individuals with PWS, the potential market opportunity for VYKAT XR and the ability of VYKAT XR to address the unmet needs of the PWS community. 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 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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