



Solenio Therapeutics Announces VYKAT(TM) XR Launch

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First prescriptions delivered to individuals with PWS

REDWOOD CITY, Calif., April 14, 2025 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced the U.S. commercial availability of VYKAT™ XR (diazoxide choline) extended-release tablets, the company's treatment for hyperphagia in patients four years of age and older with Prader-Willi syndrome (PWS), which was approved by the U.S. Food and Drug Administration (FDA) on March 26, 2025.

Prescriptions of VYKAT XR have now been delivered to the first individuals living with PWS who have been prescribed the medication.

"We are extremely pleased to begin delivering VYKAT XR, the only FDA-approved treatment for hyperphagia, to individuals living with PWS. Hyperphagia, the hallmark condition of PWS, is the leading cause of mortality in the PWS population and creates a significant burden for caregivers," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Since FDA approval, we have seen strong interest in VYKAT XR. Our team is fully prepared to meet demand and is well-positioned to execute a successful commercial launch of this first-to-market treatment. These first shipments mark an important step in our efforts to deliver this new treatment to the PWS community and are an exciting milestone reflecting our dedication to ensuring timely access to treatment."

Soleno has established a comprehensive support program, Soleno ONE™, to assist patients, caregivers and healthcare providers with access to VYKAT XR. For more information, visit www.VykatXR.com or contact Soleno ONE toll-free at 1-833-SOLENO-1 (1-833-765-3661).

Healthcare providers who want to write prescriptions can visit www.VykatXRHCP.com to complete the Start Form and initiate the process for access to treatment.

About PWS

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 $\geq 10\%$ 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.solenio.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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