



Solenio Therapeutics Announces Data Presentation Showing that Resumption of Treatment with VYKAT(TM) XR after a Randomized Withdrawal Period was Associated with Significant Improvements in Hyperphagia and Behavioral Symptoms in Participants with Prader-Willi Syndrome

May 20, 2025 8:05 PM EDT

REDWOOD CITY, Calif., May 20, 2025 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced data presented from its clinical development program of VYKAT™ XR (diazoxide choline) extended-release tablets, previously referred to as DCCR, at the Pediatric Endocrine Society (PES) Annual Meeting 2025, which was held May 15-18 in National Harbor, Maryland, USA. The presentation showed that resumption of VYKAT XR treatment in participants with PWS following a 16-week randomized withdrawal was associated with significant improvements in both hyperphagia and behavioral symptoms.

"We are pleased to share the results from our ongoing clinical development program for VYKAT XR," said Anish Bhatnagar, M.D., Chairman and Chief Executive Officer of Soleno Therapeutics. "These results support the effectiveness of VYKAT XR in managing the critical symptoms of PWS and highlight the importance of long-term, continuous treatment."

Data Presented at the 2025 Pediatric Endocrine Society (PES) Annual Meeting

Following long-term open label treatment with VYKAT XR for approximately 3 years (C602-OLE) and 16 weeks of randomized withdrawal (C602-RWP), participants who were randomized to placebo and restarted VYKAT XR in the open-label Study C614 showed improvements in hyperphagia by 13 weeks, with continued benefit through one year. Specifically, these participants showed a 6.3-point reduction in the Hyperphagia Questionnaire for Clinical Trials (HQ-CT) total score at one year —returning to levels similar to their pre-withdrawal baseline. Behavioral improvements were also demonstrated through one year, with improvements across all six domains assessed.

About PWS

The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The hallmark symptom of this disorder is hyperphagia, a chronic and life-threatening condition characterized by feelings of intense, persistent hunger, food pre-occupation, and an extreme drive to seek and consume food, which can severely diminish the quality of life for individuals with PWS 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 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.

About VYKAT XR

VYKAT XR was approved by the U.S. Food and Drug Administration (FDA) on March 26, 2025, and is now commercially available to U.S. patients.

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. 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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Source: Soleno Therapeutics