



## Soleno Therapeutics Announces Publication of Results from Pivotal Study of VYKAT™ XR in the Journal of Clinical Endocrinology and Metabolism

January 5, 2026 1:00 PM EST

REDWOOD CITY, Calif., Jan. 05, 2026 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced a publication in the peer-reviewed *Journal of Clinical Endocrinology and Metabolism (JCEM)*. The paper, titled, "Diazoxide Choline Extended-Release Tablets in Prader-Willi Syndrome: A Randomized, Double-Blind, Placebo-Controlled, Withdrawal Period Study," details results from the 16-week randomized withdrawal study (C602-RWP) of VYKAT™ XR (also known as diazoxide choline extended-release tablets, or DCCR) in children and adults 4 years and older with hyperphagia in Prader-Willi syndrome (PWS). The paper can be accessed online [here](#).

The randomized withdrawal period study was a key part of the comprehensive Phase 3 clinical program that established the efficacy and safety of VYKAT XR and supported its approval by the U.S. Food and Drug Administration (FDA) as the first and only treatment for hyperphagia in people living with PWS. This clinical program included 127 participants with over 400 patient years of drug exposure, including individuals with nearly six years of continuous treatment.

"This important study provided additional controlled data confirming the safety and efficacy of VYKAT XR in people with PWS, and we are pleased that the positive results have been accepted for publication in JCEM, the world's leading peer-reviewed journal focused on cutting-edge endocrine and metabolic research," said Dr. Anish Bhatnagar, Chief Executive Officer and Chairman of the Board of Soleno Therapeutics. "Our strong momentum since commercial launch reflects both the significant unmet need that VYKAT XR addresses as the first FDA-approved treatment for the hallmark feature of PWS – hyperphagia – as well as the meaningful therapeutic benefit that it can offer to people living with this rare and complex genetic condition."

Dr. Jennifer Miller, M.D., Professor of Pediatric Endocrinology at the University of Florida, Gainesville, and lead author of the paper, added, "The compelling results of the randomized withdrawal study highlighted in JCEM further reinforce the meaningful and sustained benefit of VYKAT XR in people living with hyperphagia caused by PWS. Notably, when study participants were transitioned to placebo during the randomized withdrawal study, we observed a significant worsening of hyperphagia, compared with those who remained on treatment with VYKAT XR. These results underscore the critical role that VYKAT XR can play in addressing hyperphagia, the most debilitating and distressing symptom of PWS, where no other effective therapeutic options are currently available."

The 16-week, randomized withdrawal period study included 77 individuals who previously completed 13-week placebo-controlled and long-term open-label Phase 3 studies. Participants were randomized 1:1 to either VYKAT XR (n=38) or placebo (n=39). The primary endpoint was Hyperphagia Questionnaire for Clinical Trials (HQ-CT) total score change from baseline to week 16. Secondary endpoints included Clinical Global Impression of Severity (CGI-S) and Improvement (CGI-I); exploratory endpoints included weight and body mass index (BMI) z-score.

### Key highlights from the publication:

- Hyperphagia worsened significantly when treatment with DCCR was withdrawn, compared to continued DCCR administration. Statistically significant increases (worsening) in HQ-CT from baseline to week 16 were observed with placebo versus DCCR ( $P=0.0022$ ).
- CGI-S and CGI-I scores favored DCCR and approached, but did not reach, statistical significance.
- Consistent with the hyperphagia response, the placebo cohort gained more weight and increased their BMI z-score more than the DCCR cohort (LS mean weight difference (95% confidence interval) -1.6 kg (-3.1, -0.1); LS mean z-score difference -0.09 (-0.17, -0.01).
- Adverse events were similar with both arms, with no serious adverse events in the DCCR treatment arm. No participant experienced an adverse event leading to study drug discontinuation.

### 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.

### 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 and was approved by the U.S. Food and Drug Administration (FDA) on March 26, 2025. For more information, please visit [www.soleno.life](http://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. 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.

**Corporate Contact:**

Brian Ritchie  
LifeSci Advisors, LLC  
212-915-2578

**Media Contact:**

[media@soleno.life](mailto:media@soleno.life)



Source: Soleno Therapeutics