



Solen Therapeutics Highlights New Data on VYKAT(TM) XR at the 2025 United in Hope: International Prader-Willi Syndrome Conference

June 25, 2025 12:00 PM EDT

REDWOOD CITY, Calif., June 25, 2025 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Solen) (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today highlighted new data on VYKATTM XR (diazoxide choline) extended-release tablets, previously known as DCCR, at the 2025 United in Hope: International Prader-Willi Syndrome Conference.

"We believe that these data reveal critical insights on the potential benefit of VYKAT XR to important subpopulations of individuals living with PWS," said Dr. Anish Bhatnagar, Chief Executive Officer and Chairman of the Board of Soleno Therapeutics. "For those individuals who are managed with strict food controls, these data suggest that they had more hyperphagia symptoms at baseline yet still saw a statistically significant, clinically meaningful benefit from treatment with VYKAT XR. These data also show that VYKAT XR can be safely administered to individuals with PWS who have pre-diabetes or diabetes, providing a benefit despite this co-morbidity."

Data are featured in two poster presentations:

Diazoxide Choline Extended-Release Tablets Significantly Reduce Hyperphagia in Patients with PWS Who Are Managed with Strict Food Controls

A primary characteristic of PWS is hyperphagia, a persistent hunger that can lead to aggressive food-seeking behavior. A common practice used in the management of individuals with PWS is to restrict access to food, but this does not address the underlying symptoms of hyperphagia.

This poster summarizes an analysis of participants in Soleno's Phase 3 studies to determine if VYKAT XR can improve hyperphagia symptoms in individuals with PWS considered to be in a highly food restricted environment.

After treatment with VYKAT XR, participants in the highly food-restricted group exhibited statistically significant ($p \leq 0.0001$), clinically meaningful reductions in HQ-CT Total scores that were often numerically greater than those observed in the less restricted group at all post-baseline timepoints through Year 3.

These data demonstrate that individuals with PWS who live with strict food controls are as likely to benefit from treatment with VYKAT XR as those who live with less strict food controls.

Safety and Efficacy of Diazoxide Choline Extended-Release in Patients with PWS who Have Pre-Diabetes or Diabetes

This poster summarizes an analysis of the safety and efficacy of VYKAT XR in individuals in Soleno's Phase 3 clinical trials who had evidence of pre-diabetes or diabetes (PD/DM) at baseline versus those who were normoglycemic.

At baseline, 60% of study participants were identified as having evidence of PD/DM. Efficacy was measured using HQ-CT scores and safety was assessed by hyperglycemia-related laboratory values and adverse events (AEs). Efficacy outcomes at Week 156 ($p < 0.0001$) were similar for the PD/DM and normoglycemic groups.

As expected, a greater proportion of hyperglycemia-related AEs were reported for participants with PD/DM as compared to those without (42.7% vs 24.0%, respectively), however these events were generally manageable. Treatment-emergent adverse event-related discontinuations rates were similarly low (4.0% in PD/DM individuals vs. 6.0% in normoglycemic individuals) regardless of baseline PD/DM status.

These data demonstrate that VYKAT XR can be administered safely and effectively to individuals with PWS who have PD/DM. Importantly, participants treated with VYKAT XR in the Phase 3 studies remained on study and had treatment efficacy, regardless of PD/DM status or occurrence of hyperglycemia-related adverse events.

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.

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



Source: Soleno Therapeutics