Soleno Therapeutics Announces Submission and EMA Validation of Marketing Authorization Application for Diazoxide Choline Prolonged-Release Tablets for the Treatment of Hyperphagia in Patients with Prader-Willi Syndrome

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REDWOOD CITY, Calif., May 22, 2025 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that Soleno's Marketing Authorization Application (MAA) seeking regulatory approval of Diazoxide Choline Prolonged-Release Tablets (previously referred to as DCCR) for the treatment of adults and children four years and older with Prader-Willi syndrome (PWS) who have hyperphagia had been validated by the European Medicines Agency (EMA).

"The validation of our MAA represents the next significant milestone in our mission to deliver this important therapy to the broad PWS community, including those in the EU," said Anish Bhatnagar, M.D., Chairman and Chief Executive Officer of Soleno Therapeutics. "Based on the data generated, DCCR has the potential to help treat hyperphagia, which is the most life-limiting aspect of PWS. We look forward to working closely with European regulators during the review process and intend to make DCCR available to patients in the EU as expeditiously as possible, if approved."

Soleno estimates that there are approximately 9,500 patients with PWS in the United Kingdom, France, Germany, Italy and Spain combined[1]. The Company has been granted Orphan Drug Designation for diazoxide choline in the EU for the treatment of PWS, which could provide Soleno with up to 10 years of market exclusivity in the EU, if approved, in addition to certain other regulatory and financial incentives.

DCCR was approved by the U.S. Food and Drug Administration (FDA) under the brand name VYKAT™ XR on March 26, 2025.

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.

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

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[1] Based on mid-point of Orphanet Birth Prevalence rate of 1 in 15,000 to 30,000

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 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, including statements regarding the regulatory approval process for Diazoxide Choline Prolonged-Release Tablets in the EU, the timing of commercialization of Diazoxide Choline Prolonged-Release Tablets in the EU, the potential market opportunity for Diazoxide Choline Prolonged-Release Tablets and the ability of Diazoxide Choline Prolonged-Release Tablets 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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