Soleno Therapeutics Presents New VYKAT® XR (diazoxide choline) Data at ENDO 2026 Demonstrating Meaningful and Durable Improvements in Hyperphagia and Behavioral Symptoms in Prader-Willi Syndrome Following Randomized Withdrawal Period

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- Participants who resumed VYKAT XR following a 16-week randomized withdrawal period demonstrated improvements in hyperphagia and behavioral symptoms as early as Week 13, with benefits continuing through 2 years
- VYKAT XR demonstrated statistically significant and sustained improvements in hyperphagia and Prader-Willi syndrome-related behaviors for up to 3 years compared to real-world data from the PATH for PWS Natural History Study

SAN DIEGO, June 15, 2026 /PRNewswire/ -- Soleno Therapeutics, a Neurocrine Biosciences (Nasdaq: NBIX) company, today announced late-breaking data at ENDO 2026 showing that resuming treatment with VYKAT® XR (diazoxide choline) extended-release tablets for two years after a 16-week randomized withdrawal period was associated with durable improvements in hyperphagia and behavioral symptoms characteristic of Prader-Willi syndrome (PWS).

"These compelling data further reinforce our confidence in VYKAT XR as a safe and effective long-term treatment for hyperphagia in individuals four years of age and older living with Prader-Willi syndrome," said Sanjay Keswani, M.D., Chief Medical Officer, Neurocrine Biosciences. "Individuals who resumed treatment following the randomized withdrawal period achieved durable improvements in hyperphagia and other PWS-related behaviors. This completes the presentation of data from our comprehensive Phase 3 development program and further confirms the long-term benefit of VYKAT XR for people living with PWS."

The VYKAT XR Phase 3 development program was conducted sequentially, including:

- A 13-week randomized, double-blind, parallel-arm study (C601) comparing VYKAT XR to placebo in participants four years of age and older with hyperphagia associated with genetically confirmed PWS
- An open-label extension study (C602 OLE) over approximately two to four years
- A 16-week, double-blind, placebo-controlled randomized withdrawal period
- An open-label long-term extension study (C614)

Study C614, the open-label long-term extension study, enrolled 77 participants (mean age, 15.3 years; 55.8% female). The study assessed whether participants who had received placebo during the randomized withdrawal period could regain treatment benefit after restarting VYKAT XR, and whether participants who remained on continuous VYKAT XR maintained benefit over time.

Hyperphagia was assessed using the Hyperphagia Questionnaire for Clinical Trials (HQ-CT) and PWS-related behaviors were assessed using the PWS Profile questionnaire (PWSP). BMI and long-term safety were also assessed. Study results included:

- Participants who restarted VYKAT XR after placebo during the randomized withdrawal showed marked improvements in HQ-CT Total Score by Week 13 (mean [SD], -4.5 [6.3]), with further improvement observed at Week 26 and at two years (-5.5 [7.1] and -6.3 [8.4], respectively).
- Participants who remained on VYKAT XR continuously showed smaller improvements (-2.7 [6.9]) at Week 13 that were sustained at Week 26 and at two years (-3.3 [5.7] and -3.1 [8.0], respectively), underscoring the benefit of uninterrupted therapy.
- Improvements across all six PWSP behavioral domains were observed at two years in participants who restarted VYKAT XR, and BMI remained relatively stable throughout.

These data show that participants who resumed VYKAT XR after randomized withdrawal experienced recovery of treatment benefit, while those who continued therapy maintained durable improvements in hyperphagia and other PWS-related behaviors. Study results were presented as, "Efficacy and Safety of Resuming Diazoxide Choline Extended-Release (DCCR) after 16-week Randomized Withdrawal in Prader-Willi Syndrome (Study C614)," which was authored by Jennifer L. Miller, M.D., University of

Florida, Gainesville.

Additional presentations at ENDO 2026:

VYKAT XR Outcomes Compared to Real-World Data from PATH for PWS Natural History Study (PATH):

Long-Term Reductions in Hyperphagia: HQ-CT Analysis
A poster presentation led by Evelien F. Gevers, M.D., Ph.D., Barts Health NHS Trust/Queen Mary University of London, reported three-year data comparing 125 VYKAT XR-treated participants from Studies C601 and C602-OLE to 229 natural history controls from the PATH for PWS Natural History Study. VYKAT XR demonstrated statistically significant and sustained improvements in hyperphagia compared with the PATH cohort at all evaluated time points (p<0.0001), with treatment differences of 6.2 points at Year 1, 6.5 points at Year 2, and 6.2 points at Year 3 on the HQ-CT Total Score.

Long-Term Behavioral Improvements: PWSP Analysis
A second presentation by Dr. Gevers reported PWSP data comparing 105 VYKAT XR-treated participants to 182 PATH controls over three years. Statistically significant improvements favoring VYKAT XR compared with the PATH cohort were observed across all six behavioral domains at Year 1 (p<0.001), Year 2 (p<0.01), and Year 3 (p<0.001). At Year 3, VYKAT XR demonstrated consistent improvements across all assessed behavioral domains versus the PATH cohort, with adjusted mean differences favoring VYKAT XR of -2.5 in anxiety, -2.4 in rigidity/irritability, -2.3 in compulsivity, -2.1 in aggressive behaviors, -1.5 in disordered thinking, and -1.1 in depression.

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 ≥10% and at least 2% greater than placebo) included hypertrichosis, edema, hyperglycemia, and rash.

Please see the full Prescribing Information, including Medication Guide.

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a leading biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs. We are dedicated to discovering, developing and commercializing life-changing treatments for patients with under-addressed neurological, psychiatric, endocrine and immunological disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, classic congenital adrenal hyperplasia, hyperphagia in patients with Prader-Willi syndrome, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas. For more than three

decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, X, Facebook and YouTube. *(*in collaboration with AbbVie)*

Forward-Looking Statements
In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements regarding the potential benefits to be derived from VYKAT XR for the treatment of Prader-Willi syndrome (PWS); the value and benefits VYKAT XR brings to patients with PWS, including its potential to support sustained and durable improvements in hyperphagia and PWS-related behavioral symptoms; and whether the results from clinical studies and other data analyses described in this press release are indicative of real-world results. Factors that could cause actual results to differ materially from those stated or implied in the forward-looking statements include, but are not limited to, the following: risks and uncertainties as to whether the data described in this press release will be replicated in additional studies or will be predictive of efficacy, safety, or other clinical outcomes in subsequent clinical studies or real-world use of VYKAT XR; risks and uncertainties associated with our business and finances in general, as well as risks and uncertainties associated with the commercialization of VYKAT XR, including the extent to which patients and physicians accept and adopt VYKAT XR; whether VYKAT XR receives adequate coverage and reimbursement from third-party payors; risks and uncertainties relating to competitive products and technological changes that may limit demand for VYKAT XR; risks associated with dependence on third parties for development and manufacturing activities related to VYKAT XR, and risks associated with managing these third parties; risks that additional regulatory submissions for VYKAT XR may not occur or be submitted in a timely manner; risks that the FDA or other regulatory authorities may make adverse decisions regarding VYKAT XR; risks that post-approval commitments or requirements for VYKAT XR may be delayed; risks that VYKAT XR may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and other risks described in Neurocrine Biosciences' periodic reports filed with the Securities and Exchange Commission, including without limitation Neurocrine Biosciences' quarterly report on Form 10-Q for the quarter ended March 31, 2026, and with respect to risks relating to VYKAT XR and Soleno Therapeutics, certain risks described in Soleno Therapeutics' annual report on Form 10-K for the year ended December 31, 2025, as updated by Soleno Therapeutics' quarterly report on Form 10-Q for the quarter ended March 31, 2026. Neurocrine Biosciences and Soleno Therapeutics disclaim any obligation to update the statements contained in this press release after the date hereof except as required by law.

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