Letter to the PWS Community

I write today to introduce myself and our company, Neurocrine Biosciences, Inc. For almost 35 years, we have focused on developing transformative treatments for people living with serious and underserved neurological, endocrine, and psychiatric conditions. Along the way, we have experienced the ups and downs of pursuing breakthrough science – learning, adapting, and persevering through both successes and setbacks.

Today, Neurocrine is a biopharmaceutical company with nearly 20 clinical development programs and five FDA-approved medicines, three of which we market ourselves. All five were first-in-class when approved, reflecting our longstanding commitment to bringing meaningful innovation to patients and their families.

This spring, we acquired Soleno Therapeutics, Inc., the company that developed and last year launched VYKAT® XR (diazoxide choline) extended-release tablets, the first and only FDA-approved treatment for hyperphagia in people aged four years and over living with Prader-Willi syndrome (PWS). Our ability to build on Soleno's work and bring this important new medicine to, and become part of, the PWS community was what excited us most about this acquisition. We are grateful for, and fully embrace, the responsibility that comes with being the new stewards of VYKAT XR. We also recognize that joining a community like this comes with an obligation to listen and learn. Trust is earned through actions, not words, and we intend to earn that trust over time through our engagement with individuals living with PWS, their families, healthcare providers, researchers, and advocacy organizations.

For many in the PWS community, the approval and availability of VYKAT XR brought new hope. We share that enthusiasm and have heard directly from families about the meaningful difference the treatment can make. To date, between Soleno's clinical trials and post-approval use, we have accumulated more than 1,400 patient-years of experience with VYKAT XR, including treatment extending over seven years. We are thrilled to see so many individuals with PWS-related hyperphagia already benefiting from VYKAT XR, so soon after its commercial launch. At the same time, broader use of the medicine has raised important questions, particularly around its safe and appropriate use. We take those questions seriously.

Our efforts to understand PWS and the role of VYKAT XR began before we acquired Soleno. During our diligence, we spent considerable time evaluating the available clinical and safety data, as well as the experiences of individuals living with PWS and their caregivers. That focus has only intensified since the transaction closed in May.

We have moved quickly to bring Neurocrine's broader clinical development, regulatory, medical affairs, and drug safety capabilities to VYKAT XR. We are comprehensively evaluating the information available to us, including experiences shared by individuals living with PWS and their caregivers, feedback from healthcare providers and external experts, information gathered through the specialty pharmacy, our adverse event reporting activities, and the broader published literature on PWS.

To generate additional important real-world data, expand our knowledge base, and further inform the continued safe prescribing and use of VYKAT XR, we have decided to move forward with a study in people with

hyperphagia in PWS who have complex health issues, including severe obesity. We plan to initiate this study in Q1 2027, once we have completed the activities necessary for trial initiation. We will keep the community informed as we finalize the clinical plan in collaboration with key leaders in the field and will publicly share the results and our learnings following completion of the study.

We are also proactively engaged with the U.S. Food and Drug Administration as this work progresses. Where the evidence identifies opportunities to strengthen education, monitoring, or clinical practice, we will act on them and communicate meaningful updates to the PWS community as appropriate.

Our approach is straightforward: follow the evidence, listen carefully, engage openly, and make decisions with the interests of individuals living with PWS and their families at the center. We will work to ensure that patients, caregivers, healthcare professionals, and the broader PWS community have the information they need to support the safe and appropriate use of VYKAT XR.

Regulatory and scientific work, however, is only one part of our responsibility. Individuals living with PWS, caregivers, healthcare providers, and advocacy organizations each bring important perspectives. That is why our conversations with the PWS advocacy community are particularly important to us.

Our commitment to the PWS community also extends beyond our stewardship of VYKAT XR. PWS is a complex condition that affects individuals and families in many uniquely challenging ways. This condition sits at the intersection of areas where Neurocrine has significant scientific and clinical experience, including endocrinology, psychiatry, neurology, and rare disease.

We are actively exploring areas of promising biology where our development programs and scientific expertise may merit exploration in aspects of PWS including and beyond hyperphagia. As that work progresses, we will look to the PWS community, clinicians, researchers, and advocacy organizations to help us understand where the greatest unmet needs remain and where science has the potential to make a meaningful difference.

I want to specifically thank the PWSA | USA, FPWR, and IPWSO teams for your welcoming engagement since our acquisition of Soleno, as well as your continued leadership on behalf of the broader PWS community. We value your partnership, passion, and candid insights.

This is still the beginning of Neurocrine’s relationship with the PWS community. We have much to learn, and we are excited about what we can accomplish together. The entire Neurocrine team looks forward to meeting and engaging with as many of you as possible in the months and years ahead.

Sincerely,

Kyle W. Gano, Ph.D.
Chief Executive Officer
Neurocrine Biosciences, Inc.

IMPORTANT SAFETY INFORMATION

What is VYKAT XR used for?

VYKAT XR is a prescription medicine used to treat extreme hunger, constant thoughts about food, and constant urge to eat that cannot be satisfied with food (hyperphagia) in adults and children 4 years of age and older with Prader-Willi syndrome (PWS).

What is the most important information I should know about VYKAT XR?

VYKAT XR may cause serious side effects, including:

- High blood sugar levels (hyperglycemia). Hyperglycemia is common during treatment with VYKAT XR and can also be severe. Hyperglycemia can lead to a condition called diabetic ketoacidosis (increased ketones in the blood) in some people who take VYKAT XR. Diabetic ketoacidosis is a serious condition that needs to be treated in a hospital and can be life-threatening.
    - Your healthcare provider will:
        - check your blood sugar levels before you start VYKAT XR, during treatment and more often during treatment if you have an increased chance of getting hyperglycemia.
        - check your HbA1c before and during treatment.
    - If you get hyperglycemia during treatment with VYKAT XR, your healthcare provider may give you medicines to treat hyperglycemia, change your dose if you already take hyperglycemia medications, or your doctor may change your dose of, temporarily stop, or permanently stop VYKAT XR.
- Tell your healthcare provider if you get any of the following signs and symptoms:
    - **hyperglycemia:** feel very thirsty, need to urinate more often than usual, have higher amounts of urine than usual, feel more hungry than usual, or weight loss
    - **diabetic ketoacidosis:** nausea, vomiting, stomach-area (abdominal) pain, feel weak or very tired or trouble breathing
- Too much fluid in your body or swelling (fluid overload). Swelling in the body from too much fluid is common during treatment with VYKAT XR and can also be severe. Your healthcare provider may decrease your dose or temporarily stop VYKAT XR if you get fluid overload. Tell your healthcare provider if you have trouble breathing or get any other signs or symptoms of fluid overload such as swelling of your legs, ankles, or feet, or unusual swelling anywhere in your body.

Who should NOT take VYKAT XR?

Do not take VYKAT XR if you are allergic to diazoxide, any ingredients in VYKAT XR or medicines called thiazides.

Before taking VYKAT XR, tell your healthcare provider about all of your medical conditions, including if you:

- have diabetes or prediabetes
- are sick
- plan to have surgery
- drink alcohol very often

- are dehydrated or have lost a lot of body fluid
- have heart problems or a history of swelling in your legs or other parts of your body that required medicine
- have liver or kidney problems
- are pregnant or plan to become pregnant. VYKAT XR may harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with VYKAT XR
- are breastfeeding or plan to breastfeed. VYKAT XR passes into your breast milk, and it is not known if it can harm your baby. Tell your healthcare provider if you plan to breastfeed during treatment with VYKAT XR

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking VYKAT XR with certain other medicines may affect the way VYKAT XR or the other medicine works and may increase your risk of side effects. Do not change your dose or stop any medicines you take, or start any new medicines, without talking to your healthcare provider first during treatment with VYKAT XR.

What are the possible side effects of VYKAT XR?

Increased hair growth all over the body, fluid overload or swelling, high blood sugar levels, and rash.

These are NOT all of the possible side effects of VYKAT XR.

Call your doctor for medical advice about side effects. You may report side effects to Soleno Therapeutics, Inc. at 1-833-765-3661 or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For further information please read the Medication Guide and full Prescribing Information for VYKAT XR.