Soleno Therapeutics, Inc.
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Changing What it Means to Live with PWS

Soleno Therapeutics is delivering meaningful solutions to individuals living with Prader-Willi syndrome (PWS) through VYKAT™ XR (diazoxide choline) extended-release tablets, the only FDA-approved treatment for patients four years and over to treat the defining feature of PWS: hyperphagia.

In 2018, Soleno began studying the therapy that became VYKAT XR. We understand how difficult living with PWS can be for families, who otherwise have had no therapeutic options for the safe and effective treatment of hyperphagia, the most disruptive aspect of this complex and rare disease.

That is why we focused our efforts on addressing the serious unmet needs of individuals living with PWS and their families. With the safety and efficacy demonstrated, we believe VYKAT XR can become the standard of care therapy for appropriate individuals four years of age and older living with PWS-related hyperphagia.

OUR TRACK RECORD

We are proud of the comprehensive clinical development program we conducted in partnership with our Principal Investigators, their study teams, the advocacy organizations, and the FDA, which led to approval of VYKAT XR.

- We are confident in the integrity and independence of our Principal Investigators and the accuracy of our data.
- The highest enrolling clinical study sites were inspected by the FDA and there were no issues identified that required a response to the FDA.
- We used a validated questionnaire, HQ-CT, to measure the primary endpoint in both double-blind, placebo-controlled clinical trials (Studies C601 and C602 randomized-withdrawal period).
- Multiple peer-reviewed articles have been published and another on the C602 randomized-withdrawal period is expected in the near future.

VYKAT XR has a well-established safety profile with over four years of data across our clinical development program in PWS, which included two double-blind, placebo-controlled studies and two open-label studies.

- Patient experience since commercial launch is consistent with the safety profile in our clinical development program and the FDA-issued prescribing information.
- We are deeply committed to the well-being of individuals living with PWS and the safe, effective use of VYKAT XR in accordance with the FDA-approved labeling.
- We are also committed to partnering with the PWS community, advocates, and healthcare providers to facilitate education and training to the broader prescribing community on the VYKAT XR FDA-approved clinical profile.
- Individuals with PWS often present with multiple co-morbidities that healthcare providers are trained to monitor, consistent with the VYKAT XR prescribing label, and we maintain strict compliance with drug safety reporting.
- Not all people living with PWS-related hyperphagia are appropriate candidates for VYKAT XR. Talk to your healthcare provider to find out more and tell them about all your medical conditions.

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Soleno has been fortunate to hear from members of the PWS community who have wanted to share their families' journeys. We are inspired and heartened by the many positive experiences.

Soleno takes safety seriously. As we see the steady growth in the adoption of VYKAT XR by families and healthcare providers, we are committed to continued education, monitoring, and transparency.

Soleno is grateful for the partnership with the PWS community throughout the clinical development program, the regulatory review process, and the FDA approval of VYKAT XR for individuals living with PWS-related hyperphagia.

Please see below for Important Safety Information for VYKAT XR (diazoxide choline) extended-release tablets.

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

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- 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 the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

For further information please read the Medication Guide and full Prescribing Information available at VYKATXR.com.