

PWS Breaking News! FDA Approves First-Ever Treatment for Hyperphagia in PWS

March 26, 2025 | Anne Fricke

We are thrilled to share with you this BREAKING NEWS for the PWS Community! The U.S. Food and Drug Administration (FDA) has officially ***approved*** **VYKAT™ XR** (diazoxide choline extended-release tablets, formerly referred to as DCCR) as the first-ever treatment for hyperphagia in Prader-Willi syndrome. This is a *monumental* victory for individuals with PWS, our families, and the entire rare disease community. This approval is a testament to the unwavering dedication of advocates, researchers, and families who never gave up hope. Today, we celebrate a future with greater possibilities, more hope, and meaningful change for those living with PWS!

We also extend our deepest gratitude to Soleno Therapeutics for their commitment to the PWS community and for working hard to make this much-needed treatment a reality for our families and loved ones. To give further details, Soleno will host a **Caregiver Now Approved Webinar on April 16th at 12:15 PM ET**. Click here to register for this live event, which will be recorded.

"PWSA | USA and our incredible volunteer advocates played a critical role in achieving this historic milestone. For years, we have been the driving force in PWS advocacy – leading the charge through our D.C. Fly-In events, direct engagement with elected officials and FDA / Center for Drug Evaluation and Research (CDER) representatives, and the powerful testimonials shared at the 2023 Externally-Led Patient-Focused Drug Development meeting and beyond.

Our continuous, boots-on-the-ground efforts ensured that decision-makers heard our voices and understood the urgent need for treatment. This approval is not just a medical breakthrough, it's the result of tireless dedication, strategic advocacy, and the unwavering belief that our loved ones deserve help and hope. I want to extend my deepest gratitude to our team and every single volunteer who helped make this moment possible. This is your victory."

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– Stacy Ward, MS, BCBA, PWSA | USA CEO

To learn more about this groundbreaking approval, we encourage you to:

*Visit Soleno Therapeutics' official VYKAT™ XR website where you'll find additional details about the newly approved treatment.
*Soleno and Medlive will host a **Caregiver Now Approved Webinar on April 16th at 12:15 PM ET**, in partnership with PWSA | USA and FPWR, where they will provide more in-depth information. You can register for this event by clicking here. This webinar will be recorded.
*Additionally, we invite you to read **Soleno's official press release** (Soleno Therapeutics Announces U.S. FDA Approval of VYKATTM XR to Treat Hyperphagia in Prader-Willi Syndrome – Soleno Therapeutics Inc.) for further details about this historic announcement.

We understand there will be many questions, and we kindly ask the PWS community to refer to Soleno's website and press release for initial information and then join the **April 16th webina**r for further discussion. Please note that PWSA | USA staff does not have additional details beyond these resources. Thank you for your patience, and let's continue celebrating this incredible milestone together!

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