THE WISCONSIN CONNECTION

The Newsletter of the Prader-Willi Syndrome Association of Wisconsin, Inc.

The mission of the Prader Willi Syndrome Association of Wisconsin, Inc. is to Support, Educate and Advocate for persons with Prader-Willi Syndrome, their families and professionals in meeting the challenges of this disability.

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Letter from the Office

Program Director

Joshua Escher

Wisconsin PWS community, I am sorry to say that this will be the final letter from the office that I write. I have accepted a new position and March 11th will be my last day with the organization. I am very sad to leave but I am very excited for what this new position holds for myself and my family in the future.

In my almost 8 years as the program director for PWSA of WI I have been very lucky to have served you all. I will always look back fondly on all the education and advocacy I have been able to provide to support you and your loved ones. Seeing smiling faces at the walk and Snowflake Ball was always its own reward for all the work myself and the board of directors put into those events.

When I left teaching, I wanted to find something where I got to make a difference in people's lives and I like to think that in some small way I got to accomplish that while working here.

Recently there have been a few updates on some medicines that are in various trial phases that may have some positive results for folks with Prader-Willi. I have included those here as well as one that is looking for individuals to participate. I have also included an article written about virtual learning and dealing with IEPs. Many of your kids are back to school in person but I have talked with a few who are not yet and things are always changing. The website that article came from is a great source for IEP knowledge so go ahead and check it out!

Keep an eye on your emails, our Facebook, and website for updates on what is going on after I am gone. Thank you again everyone for welcoming me into your world for a while. I am a better person for it!

In January we held a virtual family bingo night. We had over 60 people signed up. Folks from all over the country participated! Everyone had a really good time and winners received $10 gift cards.

Levo Therapeutics Receives Complete Response Letter from FDA for its New Drug Application for LV-101 (Intranasal Carbetocin) for the Treatment of Prader-Willi Syndrome

CHICAGO, IL, January 18, 2022 (Newswire.com) – Levo Therapeutics, Inc., a biotechnology company dedicated to using genetic insights to advance treatments for Prader-Willi syndrome (PWS) and related disorders, announced today that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for LV-101 (intranasal carbetocin) as a treatment for hyperphagia, anxiousness, and distress associated with PWS.

FDA's Division of Psychiatry concluded that, while LV-101 appears to be generally safe and well tolerated, the efficacy data available for the proposed 3.2 mg dose of LV-101 were insufficient for approval. To address this issue, FDA recommended that an additional clinical study be conducted to confirm the results of the 3.2 mg dose. Levo is currently in discussions with FDA regarding the design of this new study and continues to provide carbetocin to existing study patients.

PWS is a rare, complex, neurodevelopmental disorder that occurs in approximately 1 in 16,000 birthsi and is characterized by a false state of starvation and associated hyperphagia (unrelenting hunger), to which a deficiency in oxytocin is believed to be contributoryii. LV-101 is a selective oxytocin-receptor agonist with over 200 patient-years of safety data collected to date in individuals with PWS.

"We are disappointed by the outcome of FDA's review of our application and the continued lack of treatments for the most significant symptoms of the syndrome," said Sara Cotter, CEO of Levo Therapeutics. "We are hopeful that our discussions with FDA regarding the next study will be productive and that we can initiate enrollment of a confirmatory study later this year."

"As the highest enrolling site in both the phase 2 and phase 3 PWS studies of intranasal carbetocin, we have seen the exciting potential of this therapy," said Elizabeth Roof, M.A., of Vanderbilt University. "We are committed to again being a part of the next study of carbetocin and look forward to collecting the data needed to enable access to this important treatment option."

"We remain steadfast in our support of carbetocin and all potential treatments for our community," said Theresa Strong, PhD, founding member and Director of Research Programs at the Foundation for Prader-Willi Research. "We hope that, going forward, FDA will recognize the tremendous unmet need and exercise the flexibility it has when considering new products for rare, serious diseases such as PWS."

"Currently, there are no therapies approved by FDA to treat the most challenging aspects of PWS, namely the constant hunger and distress that substantially impact patients and families," said Paige Rivard, MBA, CEO of the Prader-Willi Syndrome Association USA. "PWSA | USA remains committed to advocating for treatments for the PWS community and we urge the PWS community to consider enrollment in the next study of this important potential treatment."

Caregivers who are interested in being contacted as details become available are encouraged to provide their information at www.pwsstudy.com.

About Intranasal Carbetocin

Carbetocin is an analog of the naturally-occurring neuroendocrine hormone oxytocin. Carbetocin was designed to have an improved receptor binding profile compared to oxytocin, with greater affinity for the oxytocin receptor and lower affinity for related vasopressin receptors. Through our licensor, Ferring Pharmaceuticals, carbetocin is approved in over 90 countries outside the United States for the prevention of uterine atony and excessive bleeding during cesarean section delivery, as well as newly approved in the EU following vaginal birth, with an estimated cumulative exposure of over 10 million patients. LV-101 is an investigational intranasal form of carbetocin, intended to be administered to patients with PWS three times each day before meals. LV-101 has been granted orphan drug and Fast Track designations from the U.S. Food and Drug Administration (FDA).

About Levo Therapeutics, Inc.

Levo Therapeutics is a biotechnology company dedicated to using genetic insights to advance treatments for Prader-Willi syndrome and related disorders. To learn more about Levo, please visit www.levotx.com, or follow us on Twitter and LinkedIn.

For Further Information:

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Pitolisant for the Treatment of Excessive Daytime Sleepiness in Prader-Willi Syndrome

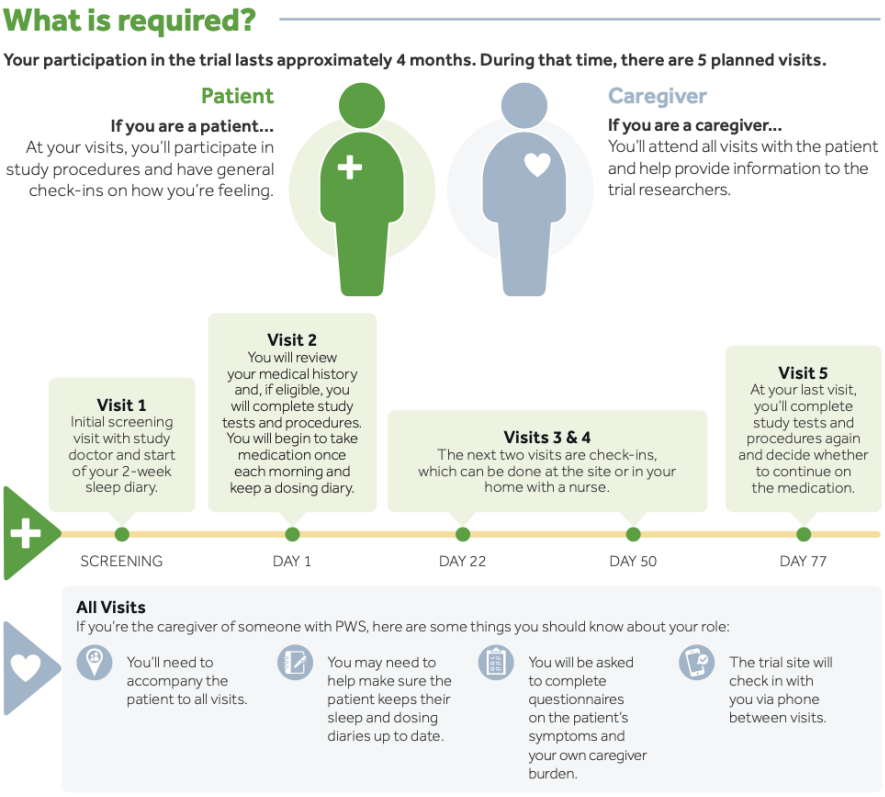
Study Purpose

The primary objective of this study is to evaluate the safety and efficacy of pitolisant compared with placebo in treating excessive daytime sleepiness (EDS) in patients with Prader-Willi syndrome (PWS) ages 6 to 65 years.

Secondary study objectives are to evaluate the impact of pitolisant on:

- Behavioral symptoms
- Cognitive function
- Safety and effectiveness of long-term treatment
- Caregiver burden

The study will consist of a Screening Period, an 11-week Double-Blind Treatment Phase (including a 3-week Titration Period and an 8-week Stable Dose Period), and an optional Open Label Extension (OLE) Phase. The OLE Phase will be multi-year in duration and will continue until either pitolisant is approved for patients with PWS or the Sponsor elects to terminate the study.



Approximately 60 patients who meet all eligibility criteria will be randomized at the Baseline Visit in a 1:1:1 ratio to low dose pitolisant, high dose pitolisant, or matching placebo. In the Double-Blind Treatment Phase, patients will be titrated to their randomized stable dose of study drug during the 3-week Titration Period.

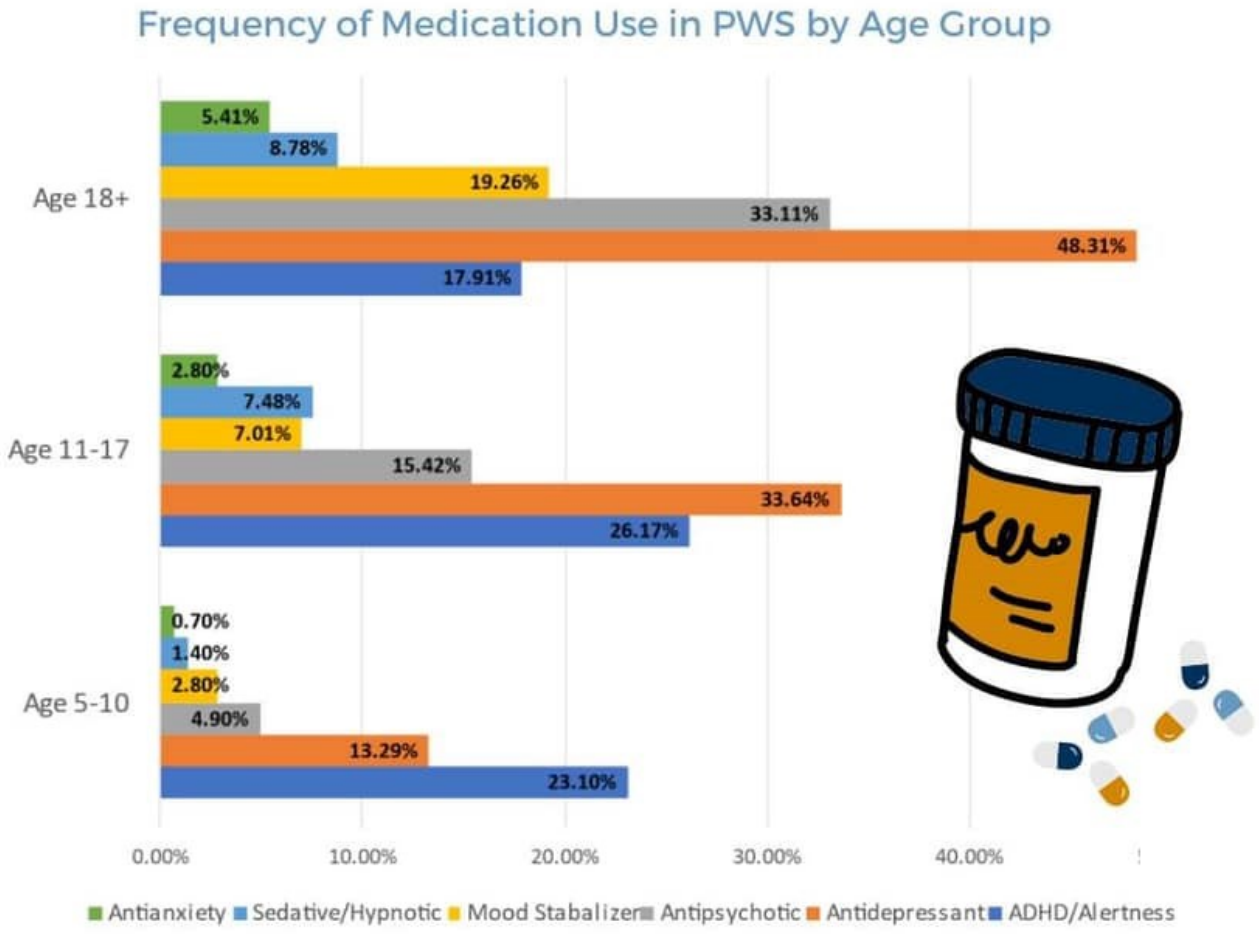
After completion of the 3-week Titration Period, patients will continue to take study drug at their randomized stable dose once daily in the morning upon wakening for an additional 8 weeks of blinded treatment (Stable Dose Period). The duration of the Double-Blind Treatment Phase will be 11 weeks.

Following the 11-week Double-Blind Treatment Phase, eligible patients will be given the opportunity to participate in an optional OLE Phase. During the OLE Phase, all eligible patients will receive treatment with open-label pitolisant and will undergo titration during a 3-week Titration Period to a maximum target dose based on their age. At the end of the 3-week Titration Period, patients will continue to take their target dose of pitolisant once daily in the morning upon wakening until the end of the study.

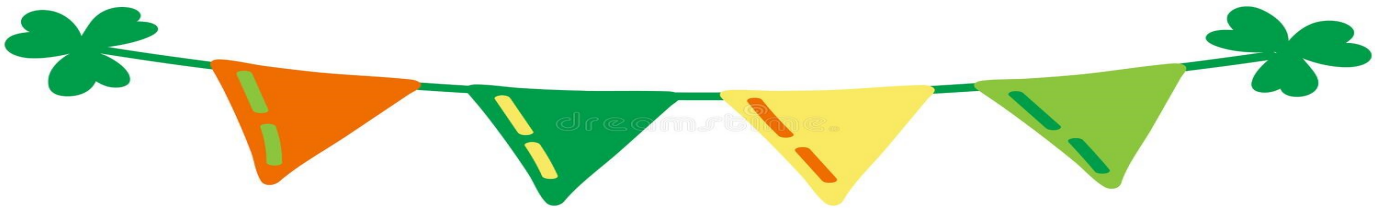
To watch the recording of the webinar about this study: https://youtu.be/1GMy-P3cBK8

YOU CAN HELP US LEARN MORE ABOUT MEDICATION USE IN PWS

It is common for people with PWS to take **one or more medications** to address behavior and psychiatric challenges.



Complete or update your medications surveys at www.pwsregistry.org



IEP and 504 Accommodations for Distance and Online Learning.

ByLisa LightnerDecember 6, 2021

Online and Virtual Learning Accommodations

Some kids really struggle with online distance learning, and need some accommodation ideas. Particularly those with attention, sensory, and other related issues.

And, there are a lot of kids out there who loathe Zoom and online classes. Some love it, others not so much. But, even as kids return to in-person learning, many students will still experience distance learning on snow days. So, it's a good idea to have ideas that work established for accommodating your child during distance learning.

If your child struggles with some of these issues in a typical classroom, it's not realistic to think that they would not face similar or related issues during online learning.

If a student cannot focus on the teacher in the classroom, doing the same online will be a challenge.

They might be able to ignore the distracting classmate who sits behind them while at school. In a virtual learning setting, all of their classmates are right there in front of them. Kind of hard to ignore, don't you think?

And, Zoom fatigue is a thing. It exists.

Accommodations for Online Learning

Determine the issue. Ask them.

That's your first step. If your child loathes online learning or is refusing to do it, ask them why. Let them be heard and validated.

From there, brainstorm and decide what needs to be done.

Progress begets progress…and failure begets more failures. If your child is unsuccessful at distance learning for even one snow day (albeit not their fault), that can put them behind.

Most school curricula is cumulative. Miss one snow day of distance learning, and then you're behind the next day…which deflates confidence. So then they're behind the next day and the next day and the day after that. This is how learning issues snowball. (no pun intended)

Barriers to Distance Learning

Some of the barriers to learning online for many IEP/504 students, including ADHD:

- Your child takes longer to learn new things, steeper learning curve.
- Cannot see/hear sufficiently.
- Endurance: Classes are too frequent or too long.
- Same issues as in-person classroom: Distractions, focus, need for pre-teaching or re-teaching, need for pull out or smaller group.
- Sensory Issues: too bright, too loud, too much conflicting data to process.
- Processing Issues

Executive Functioning Issues and Distance Learning

If your child struggles to manage a locker, homework assignments and other things at in-person school, why would distance learning be any different? Different teachers, a new schedule, log ins, passwords…of course they are going to need EF help at home too!

Adding Distance Learning Accommodations to an IEP or 504

As a side note, my professional advice would be to not overthink this and make a mountain out of a molehill. Start small. A short email to the teacher with "My son is experiencing this, and I want classes to be successful, so can we try XYZ and see if that helps?"

I wouldn't do a full-blown formal request to meet, asking for PWN, etc. You have your email paper trail if you need it.

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One of the key words coming out in all the pandemic guidance is reasonable. If your request is reasonable, you shouldn't expect resistance. But reasonable is subjective.

Also know that as the pandemic dragged on, school districts and states got better at this. Early on, this was so new to everyone and there was a lot of confusion. My point: There shouldn't be too many "well, we can't do that because…."

Because the same IEP rules do apply–if it's appropriate for what the child needs , it can be done. While I hope you won't be met with resistance, you might be. So go with your gut and keep pushing.

Distance Learning Accommodations- The Child's Environment

Do what you can to set your child up for success, and that starts with technology and ergonomics. Your home does not have to be a mini classroom. Use what works, even if that is a bean bag chair.

1) Keep your school days in a routine with bedtimes, eating, showering etc. (I have become laxer with bedtime, but I am consistent–an hour later every night, that's it)
2) Comfortable seating with solid line-of-view for the device being used, plus any books or writing materials. (In other words, I don't care if my kid curls up on his bed to do this, but he still needs to be able to see the screen and pay attention.)
3) Use Chat features. Zoom and other sites have features that allow a student to ask a question or raise their hand.
4) Lighting and noise optimum, no distractions.
5) Bathroom, drink of water, etc. prior to class beginning.
6) If your home internet is not fast enough or you don't have wifi, contact Comcast about their low-income options.
7) Toys, pets, etc. all put away for the duration of classwork.
8) "Heavy Work" before and after online classes and have those items handy for sensory breaks.
9) Ensure that kids are getting enough physical activity–it doesn't have to be a parent-led activity.
10) Consider a contract with your kids or some type of incentive to work toward. What motivates them?

Once you have tried options for your child's environment, or you've spoken to him, and that's not it, it's time to brainstorm together on what may work. Here are a few options. First, look at your child's current IEP or 504, and see what is in there as far as accommodations for class. See what might work for this new setting. As always, self-advocacy is the goal. Consider having your child send the email asking for the accommodations.

Distance Learning Accommodations

Other ideas:

1) Record the class/lecture: This will allow your child to re-watch or review the material that was taught or discussed.
2) Ask the teacher for PowerPoint or whatever presentation is being given to the class for your child to preview/review.
3) For group zoom chats (or similar): Ask the teacher to mute other students during the class, or turn their video off so only the name appears.
4) Ask if your child can do audio-only, so they only have one sense to process.
5) Use features that are built into the software that the school is using, like Breakout Rooms and Chat Features.
6) If endurance is an issue, talk with the teacher about perfect attendance and what is mandatory. If your child reviews the video later, can that count? Some kids will need reduced workload or alternative assignments. Keep this strengths-based, what can your child do in lieu of attending 3 zoom classes a day if that's too much?
7) If your child has to share a device with a sibling, your child may need the class(es) to be recorded because your child cannot attend it live.

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8) Tell the teacher that your child may leave mid-session to take a sensory break.

9) Look online at the settings, see if you can set up something for closed captioning if appropriate.

10) I don't want to list other specifics like what they might already be receiving in the classroom, for things like ADHD. Accommodations like "more time to complete assignments" should be happening anyway. Again, you may need to revisit what your child receives in school, and adjust it to distance learning.

Distance Learning is Here to Stay

Virtual distance learning saw a huge surge in popularity recently, for obvious reasons. But, many families are finding that this option really works for them and are going to stick with it.

Even if your child returns to in-person learning as it becomes available, this list of IEP and 504 accommodations is good to have in the event that your child has an extended illness or otherwise needs homebound instruction.

Good luck, you got this!

This article was written for and appears on **adayinyourshoes.com**. This site is a great resource for parents going through the IEP process.

Soleno Therapeutics Provides Regulatory Update on DCCR for the Treatment of Prader-Willi Syndrome

January 24, 2022

REDWOOD CITY, Calif., Jan. 24, 2022 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno or the Company) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today provided an update following recent interactions with the U.S. Food and Drug Administration (FDA) regarding the development of once-daily DCCR (diazoxide choline) extended-release tablets for the treatment of Prader-Willi syndrome (PWS).

On January 20, 2022, the Company received official meeting minutes from the December 21, 2021, Type C meeting with the FDA's Division of Psychiatry. The purpose of the meeting was to discuss the adequacy of the data submitted by Soleno to the FDA in October 2021 to support a potential New Drug Application (NDA) submission for DCCR for the treatment of PWS, as well as possible ways to generate additional controlled clinical data. The FDA indicated they were receptive to a study design involving participants currently enrolled in Study C602, the Company's ongoing open-label extension study to generate the additional control data necessary to support an NDA. The Company expects to submit a study proposal shortly and, if acceptable, intends to initiate the study thereafter.

"We appreciate the constructive dialogue with the FDA and the potential to obtain additional controlled clinical data from participants already enrolled in C602. This approach would significantly reduce the time and cost to obtain the necessary data," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Importantly, we are continuing our preparations for an NDA submission for DCCR while the additional data are being collected."

Study C602 is an open-label extension study comprised of patients who completed DESTINY PWS, an international, multi-center, randomized, double-blind, placebo-controlled study of DCCR.

About DCCR (Diazoxide Choline) Extended-Release Tablets
DCCR is a novel, proprietary extended-release dosage form containing the crystalline salt of diazoxide and is administered once-daily. The parent molecule, diazoxide, has been used for decades in thousands of patients in a few rare diseases in neonates, infants, children and adults, but has not been approved for use in PWS. Soleno conceived of and established extensive patent protection on the therapeutic use of diazoxide and DCCR in patients with PWS. The DCCR development program is supported by data from five completed Phase 1 clinical studies in healthy volunteers and three completed Phase 2 clinical studies, one of which was in PWS patients. In the PWS Phase 3 study, DCCR showed promise in addressing hyperphagia, the hallmark symptom of PWS, as well as several other symptoms such as aggressive/ destructive behaviors, fat mass and other metabolic parameters.

About Soleno Therapeutics, Inc.
Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company's lead candidate, DCCR extended-release tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in a Phase 3 clinical development program. For more information, please visit www.soleno.life.

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WISCONSIN Prader-Willi SYNDROME ASSOCIATION (USA) SAVING AND TRANSFORMING LIVES

PWSA of WI, Inc.'s Event Calendar		
On the Move Walkathon	Saturday May 7th, 2022	Roosevelt Park, Oconomowoc, WI