



# 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*



Hi folks, I hope that this newsletter finds everyone happy and healthy during this holiday season!

As I write this the sun is disappearing and I can't tell you how happy I am that in a few days we will start getting more and more of that glorious glowing ball in that sky again. In the meantime, do like I do and try to get outside and feel that sun on your face at least a little every day possible. It is good for the soul!

I always remind folks this time of year that if you have a child in school still, those IEPs are coming. If you have any concerns or you just want some support or advocacy, I am here to help. Even now where we might not be able to be in the same room, I am fully able to jump on a video conference. If you flip to page 3 and 4 in this newsletter I have added some information pertaining to what can be done if your child may need more services due to in person schooling being shut down this year.

This has been a challenging year for everyone and honestly I am here even if you just need a sympathetic ear. Don't ever be afraid to call with even basic questions, that is why I am here and if I can't find answers for you, I will figure out who can.

HAPPY  
**2021**  
NEW YEAR

*In Loving Memory of Joan Kieffer.*



*Many generous donations were made in honor of Joan. We send her family and friends our deepest condolences.*

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

December 11, 2020

**Soleno intends to submit plans to FDA to conduct further analyses of clinical data from completed and ongoing studies of DCCR, together with external, natural history studies**

REDWOOD CITY, Calif., Dec. 11, 2020 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. ("Soleno") (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced the receipt of official meeting minutes from the November 12, 2020, Type C meeting with the U.S. Food and Drug Administration (FDA) regarding the development of once-daily Diazoxide Choline Controlled Release (DCCR) tablets for the treatment of Prader-Willi Syndrome (PWS). The meeting minutes confirmed the discussion with the FDA regarding the potential adequacy of data from completed and ongoing studies with DCCR, together with external, natural history studies to support a New Drug Application (NDA) for DCCR for the treatment of PWS. Soleno intends to submit formal plans for these analyses, which the FDA has stated it is committed to reviewing.

"We appreciate the guidance provided by the FDA and are finalizing our plans to conduct the analyses that were discussed at this meeting and look forward to submitting them to the FDA," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "While we hope that these data, together with the additional analyses, will suffice as adequate for an NDA, we cannot, at this time, exclude the possibility that the FDA will require us to conduct an additional controlled clinical study. We look forward to working with the FDA to ensure that the necessary data and information are compiled for the NDA, which we are currently preparing to submit in the second half of 2021."

## About PWS

The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births in the U.S. The hallmark symptom of this disorder is hyperphagia, a chronic feeling of insatiable hunger that severely diminishes the quality of life for PWS patients and their families. Additional characteristics of PWS include behavioral problems, cognitive disabilities, low muscle tone, short stature (when not treated with growth hormone), the accumulation of excess body fat, developmental delays, and incomplete sexual development. Hyperphagia can lead to significant morbidities (e.g., stomach rupture, obesity, diabetes, cardiovascular disease) and mortality (e.g., choking, accidental death due to food seeking behavior). In a global survey conducted by the Foundation for Prader-Willi Research, 96.5% of respondents (parent and caregivers) rated hyperphagia as the most important or a very important symptom to be relieved by a new medicine. There are currently no approved therapies to treat the hyperphagia/appetite, metabolic, cognitive function, or behavioral aspects of the disorder. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the U.S. and EU, and Fast Track Designation in the U.S.

## About Diazoxide Choline Controlled-Release (DCCR) Tablet

Diazoxide Choline Controlled-Release tablet is a novel, proprietary extended-release, crystalline salt formulation of diazoxide, which 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 I clinical studies in healthy volunteers and three completed Phase II clinical studies, one of which was in PWS patients. In the PWS Phase III 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, Diazoxide Choline Controlled-Release (DCCR) tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in a Phase III clinical development program. For more information, please visit [www.soleno.life](http://www.soleno.life).



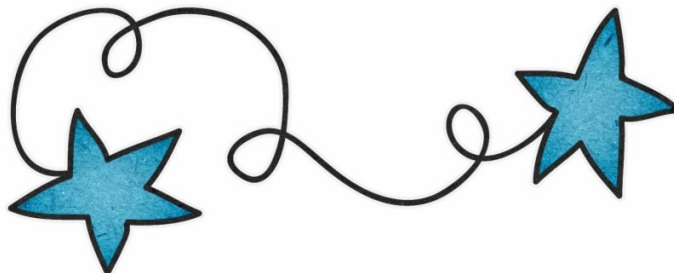
Continued on page 3

Continued from page 2

**Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding timing of any regulatory process or ultimate approvals and determining a path forward for DCCR for the treatment of PWS. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including the risks and uncertainties associated with market conditions, as well as risks and uncertainties inherent in Soleno’s business, including those described in the company's prior press releases and in the periodic reports it files with the SEC. The events and circumstances reflected in the company's forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, the company does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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**Thank You!**

To everyone who participates in employee matching programs with their employers that have chosen us as your charity, thank you! We do not always receive a notification of who to acknowledge for these donations so we wanted to let you all know how much we appreciate you.

If your employer does donation matching, consider donating through it to us. If you aren’t sure how, check with your H.R. person or give us a call.

As we pass through the holidays many educators will begin working through their IEP caseloads. It will be very important to know your rights this year, especially if your child has had to miss out on some services due to covid restrictions, etc. Below I have compiled some important sections from a WI DPI document released this summer to better explain some of the processes. To read the entire document go to <https://dpi.wi.gov/sites/default/files/imce/sped/pdf/covid-additional-services-qa.pdf>

\*\*\*Please note that when the term “additional services” is used it is to mean services that may be needed because school buildings were closed to in-person instruction.\*\*\*

**What should parents and families know about “additional services”?**

To receive additional services, your child must be receiving special education services through an IEP.

- School staff that work with your child and the IEP team should work together, along with the parent, to discuss adding or not adding additional services to the IEP.
- Parents and families know their child best and spend the most time with them during school closure. Be prepared to share what you have seen about your child's learning

Continued on page 4

Continued from page 3

- Services must be in addition to and not replace your child's current education.
- IEP teams are not required to replace every minute your child missed special education services during the school closure, and in most cases, this would not be possible.
- Additional services are not automatically required if your child did not receive all of the services as specified in their IEP.
- The amount and type of additional services are what your child needs to address loss of skills or knowledge so your child can make progress and catch up more quickly and/or address any new needs your child may have since school buildings closed.
- In deciding about where additional services will be provided, IEP teams must still consider what would be the least restrictive environment for your child's education.

Parents can learn about additional services so they are ready to participate in the decision to determine whether or not their child needs additional services.

### **Do we need to have an IEP team meeting to make a decision about additional services for my child?**

No. However, parents must be included in the decision about additional services. The parent and IEP team can decide on additional services with or without an IEP team meeting.

- If there is not an IEP meeting, the school will contact you to discuss and decide if additional services are necessary and if you agree.
- If you agree with additional services, the school must send you a revised IEP that tells you the changes made to the IEP and when those changes will begin.
- The school will send a form, letter, or statement that says the parent agreed with the changes made to your child's IEP.
- The parent has the right to request an IEP meeting to discuss changes to the IEP at any time.

Families can make the decision of whether or not to hold an IEP meeting. When parents participate in the decision for additional services, parents can ask questions to make sure they understand what the changes in the IEP will mean for their child. If the parent does not agree with the additional services decision, parents have the right to dispute resolution options (see question #20).

### **When should we make a decision about additional services for my child?**

Additional services decisions should take place within 6 months of the first day of the school year.

- Your child's teachers should work with your child to know what progress your child made during the time school buildings closed and identify your child's current general and special education needs.
- Schools should try to meet with you sooner if your child did not have any instruction or very little instruction during the time school buildings were closed.
- Schools should try to meet with you sooner if your child needs new special education instruction or support that your child did not receive before school buildings closed.
- If your child graduated or exited out of school at age 21, the school should meet with you before school begins.
- The parent may request an IEP meeting more than once a year to review and revise your child's IEP. Any IEP meeting can include making decisions about additional services so your child receives what they need to receive a free and appropriate public education.

Parents can contact their child's IEP team to decide the best time to meet, share information and concerns about their child's learning, and review and revise the IEP.

As I said, this is just a part of a much larger document with tons of great info. If this was helpful to you I would suggest checking out the rest of it: <https://dpi.wi.gov/sites/default/files/imce/sped/pdf/covid-additional-services-qa.pdf>

## Healthy Turkey Chili

### Ingredients

2 lbs ground turkey extra lean  
 3 garlic cloves minced  
 2 large onions finely chopped  
 4 large celery stalks chopped  
 3 large bell peppers chopped  
 14 oz can low sodium red kidney beans drained & rinsed  
 14 oz can low sodium white beans drained & rinsed  
 28 oz can tomato sauce or crushed tomatoes low sodium  
 2 cups chicken or vegetable broth low sodium  
 1 tbsp chipotle pepper in adobo sauce minced  
 1 tbsp chili powder low sodium  
 1 tbsp taco seasoning low sodium  
 1/2 tsp salt  
 Ground black pepper to taste  
 Oil for frying  
 Lime, cilantro, cheese, yogurt, chips etc. for serving

### Instructions

1. Preheat large 5-6 quart Dutch oven, heavy bottom pot or ceramic non-stick skillet on high heat and add ground turkey. Cook until small pieces form or about 5 minutes, stirring and breaking into small pieces with spatula constantly. Transfer to a bowl or large slow cooker, and set aside.
2. Return skillet or pot to medium heat and swirl a bit of oil to coat. Add garlic and onion, sauté until translucent or 5 minutes, stirring occasionally.
3. Add celery and bell peppers, sauté for 5 more minutes, stirring occasionally. If using slow cooker, transfer there, or leave in a dutch oven. Then to either add red kidney and white beans, tomato sauce, broth, chipotle pepper, chili powder, taco seasoning, salt and pepper.
4. Cover, bring to a boil, reduce heat to low and simmer for about 1 hour. In slow cooker, cook on Low for 8 hours or on High for 4 hours.
5. Serve warm with your favorite toppings!

### Nutrition

Serving: 2cups | Calories: 274kcal | Carbohydrates: 28g | Protein: 35g | Fat: 3g | Saturated Fat: 1g | Cholesterol: 62mg | Sodium: 499mg | Potassium: 545mg | Fiber: 9g | Sugar: 6g | Vitamin A: 1937IU | Vitamin C: 60mg | Calcium: 26mg | Iron: 1mg

*Recipe taken from ifoodreal.com, author Olena Osipov*



Save the Date!

The 2021 PWSA | USA National Convention

June 22<sup>nd</sup> - 26<sup>th</sup>, 2021 | Lake Buena Vista Palace

**We want to thank everyone that participated in our first ever Virtual Pub Quiz!  
We had 13 teams participate and it was a really fun night.**

An extra special thanks to our Pub Quiz sponsor: **Affeldt Law Offices, S.C.** Affeldtlaw.com

**A big thank you to all of our question sponsors:**

John Rockenbach-*In Honor of Tony Dorn*

*Honoring Tony Dorn with love from the Bramson, Conlin, Fitzgerald, Opsal, Talbott, & Witte-Davis families.*

John & Cathie Lehman

Cathy Hazzard-*Friends of Tony Dorn*

Waggin Tails Dog Spa-*In honor of Tony Dorn*

CGC, Inc-*In honor of Tony Dorn*

Rebecca Norman-*In honor of Tony Dorn*

Erik Martin-*Pantheon misses working with all of our clients and hopes to see everyone back safe and soon!*

Tom & Agnes Hughes-*Don't strain your brain!*

**We will be doing another one of these in January so keep your eyes peeled for more information!**



**Virtual Family Bingo is coming! Stay tuned to our website and social media pages for info!**



**Do you know someone with Prader-Willi who no longer has family to provide them with gifts on their birthday or Christmas?**

PWSA of WI has a gift giving program for these folks! Please contact us for more information so we can make their day.



Do you have a teacher, doctor, care provider, or other professional that you think deserves to be recognized for their service to the PWS community? We want to reward them! Visit our website at <https://pwsaofwi.org/ProRecognition> and fill out an application today! Each winner will receive a certificate, a card, and a \$50 gift card.

## Did you know?

The Katie Beckett Program is a special eligibility process that allows certain children with long-term disabilities, mental illness, or complex medical needs, living at home with their families, to obtain a ForwardHealth\_card.

Children who are not eligible for other Medicaid programs because the income or assets of their parents are too high may be eligible for Medicaid through the Katie Beckett Program. A child may be eligible for this source of Medicaid even if they are currently covered under a private health insurance policy.

To find out more and check your eligibility:

<https://www.dhs.wisconsin.gov/kbp/index.htm>



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**PWSA of WI, Inc.'s Event Calendar**