

# THE WISCONSIN CONNECTION

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PWSA of WI, Inc. is a  
chapter of PWSA (USA)

Website: www.pwsausa.org

*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.**



*Joshua Escher*

*Program Director*

## Letter from the Office

The sun is shining, the snow is melted, and as I type this spring is only a few days away! I hope this newsletter finds everyone happy, healthy, and looking forward to a more positive year.

I have been lucky enough to get to see some of your smiling faces over the last few months. We held our second Virtual Pub Quiz trivia night back in February and I got to watch everyone flex their gray matter. I also hosted two bingo nights that were a ton of fun. Bingo night three is already schedule for April 17th so keep an eye out on the website and socials for registration.

Unfortunately we do not expect to be holding our annual walk Mother's Day weekend this year but keep an eye out. We will still have plans for activities during May for Prader-Willi awareness. Crossing fingers we will also be able to hold the walk so everyone can get together a little later this year.

As a reminder, as the school year ends, many of you probably have IEP meetings coming up. The pandemic has changed a lot of things for everyone around schools and those IEPs may need some serious tweaks. I am always available to provide support in these situations. Give me a call. I'll be here for you!

## *In loving memory*

PWSA of WI has received many generous donations in memory of Adam Christman who was taken from us far too soon. We send our love out to his family and friends in this difficult time.



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

REDWOOD CITY, Calif., March 08, 2021 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. ("Soleno") (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).



Subsequent to the previously disclosed Type C meeting with the FDA on November 12, 2020 regarding the potential adequacy of data from studies with DCCR to support a New Drug Application (NDA) for the treatment of PWS, Soleno submitted additional analyses to the FDA from the Company's Phase 3 trial, DESTINY PWS (C601). These data were from study visits that were completed prior to the significant disruptions caused by the COVID-19 pandemic. The data analyses showed statistically significant changes for DCCR compared to placebo in the primary and key secondary endpoints. Following its review of the data submitted by Soleno, the FDA informed the Company on March 5, 2021 that an additional controlled clinical trial will be necessary to support an NDA submission for DCCR in PWS.

"We intend to continue the dialogue with the FDA to ensure that DCCR is approved for individuals with PWS as expeditiously as possible," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Based on the totality of data generated to date, we remain confident in DCCR's potential to address the unmet need for a safe and effective treatment option for PWS patients. We are currently evaluating the appropriate next steps for our DCCR program."

### 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., obesity, diabetes, cardiovascular disease) and mortality (e.g., stomach rupture, 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 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](http://www.soleno.life).

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**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.

**Corporate Contact:**

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 LifeSci Advisors, LLC  
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**\*\*A note about the press release above. The Prader-Willi community is disappointed about this decision and are currently advocating to the FDA that they reconsider this decision.\*\***

**PWS Joint Advocacy Initiative**

**26,640** supporters signed-on in favor of an FDA review of DCCR for PWS

**Who Participated in the Sign-On?**

Participants came from **89 Countries**

**97%** of parents, caregivers, healthcare providers and people with PWS would like the option to give DCCR to their loved one with PWS if approved.



**Did you know PWSA of WI has a card club for individuals with PWS?!**



Contact our program director at [progdir@pwsaofwi.org](mailto:progdir@pwsaofwi.org) to have birthday cards and seasonal cards sent to your loved one with PWS!

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.





**The PWSA USA 36th National Convention is going to be virtual this year!**

What does this mean to you? It will be free to attend. No travel costs, no convention fees. If you have ever wanted to participate in the national convention but couldn't for any reason, this year is the year to do it.

There will be 5 different days focused towards different groups:

**June 22nd**-Professional Providers

**June 23-24**-Medical/Scientific

**June 25-26**-General Conference

Registration for the conference can be found at [pwsausa.org](http://pwsausa.org).

Share with educators, caregivers, healthcare providers, and anyone else you might think would benefit! (Many professionals can use events like this towards credentials, etc.)

**PWSA of WI is a proud sponsor of the National Convention at the Sandcastle level. We felt it was important to support this event as it is available to everyone in our state who would like to participate this year.**

## **Statement from Members of the Clinical Advisory Board (CAB) Regarding People with PWS and COVID-19 Immunization**

December 15, 2020 PWSA | USA

The types of vaccines now available against COVID-19 use mRNA technology. This type of vaccine has been under development for many years and, unlike other immunizations, does not place a weak or inactive germ into the body, but instead teaches cells in our body to make an immune response that then produces antibodies which provide protection if exposed to COVID-19.

Given the scale of the pandemic with the impact upon lives and long-term health, experts from the US (FDA, CDC) and Europe (MHRA, EMA) have carefully reviewed data from very large clinical studies conducted by the vaccine developers and provided emergency authorization approval to expedite availability to the public. Reported side effects from the vaccines currently available (Pfizer and Moderna) are rare, but their use in those with a history of severe allergies should be discussed with a medical adviser and possibly avoided. Studies are currently underway looking at the safety of the vaccine in children.

PWSA | USA understands that decisions regarding COVID-19 vaccination is a personal/family decision, but advocates for vaccination, particularly among those with Prader-Willi syndrome who are at an increased potential risk for COVID-19 complications (i.e., those individuals with severe obesity, sleep apnea, diabetes and cardiovascular disease).





## Lemon Thyme Chicken

### Ingredients

3 tablespoons all-purpose flour  
 1/2 teaspoon salt  
 1/4 teaspoon pepper  
 4 boneless skinless chicken breast halves (6 ounces each)  
 2 tablespoons olive oil  
 1 medium onion, chopped

1 tablespoon butter  
 1/2 teaspoon dried thyme  
 1 cup chicken broth  
 3 tablespoons lemon juice  
 2 tablespoons minced fresh thyme

### Directions

- 1) In a small bowl, combine flour, salt and pepper. Set aside 4-1/2 teaspoons for sauce. Sprinkle remaining flour mixture over both sides of chicken.
- 2) In a large nonstick skillet, heat oil over medium heat. Add chicken; cook until juices run clear, 7-9 minutes on each side. Remove and keep warm.
- 3) In the same pan, melt butter over medium-high heat. Add onion; cook and stir until tender, 3-5 minutes. Stir in thyme and reserved flour mixture until blended. Gradually stir in broth and lemon juice, scraping up any browned bits from bottom of pan. Bring to a boil; cook and stir until thickened, about 2 minutes. Serve over chicken. Sprinkle with thyme.

### Nutrition Facts

1 chicken breast half with 1/4 cup sauce: 308 calories, 14g fat (4g saturated fat), 103mg cholesterol, 647mg sodium, 8g carbohydrate (2g sugars, 1g fiber), 36g protein. Diabetic Exchanges: 5 lean meat, 2 fat, 1/2 starch.



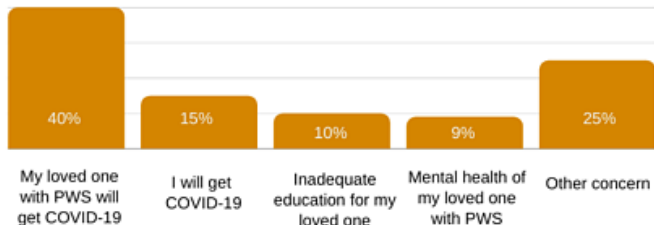
On February 20th we held our 2nd Virtual Pub Quiz. 11 teams competed for the title. In the end Team Zag knocked off reigning champions Social Quizstancing. Thanks to all the teams for participating!

## IMPACT OF COVID ON PWS FAMILIES



### #1 COVID-19 Concern Among Caregivers

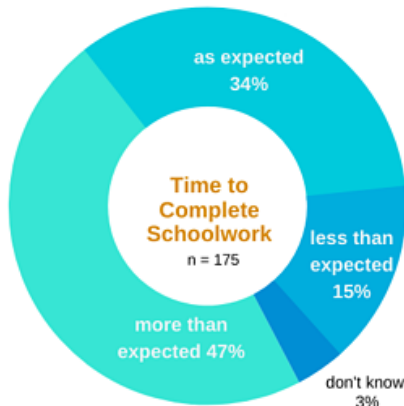
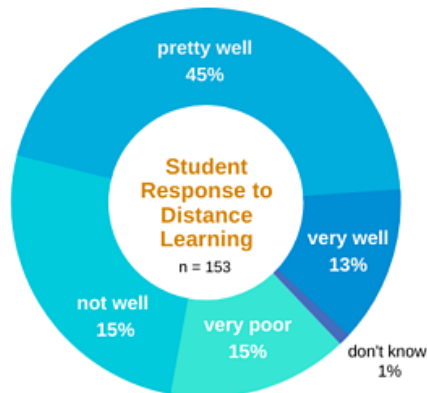
n = 269



85% of caregivers report they are under more stress and 40% report getting less sleep.



### Distance Learning in School Age Children



WWW.PWSREGISTRY.ORG

AUGUST 2020



**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.



## Become a PWSA of WI Member!

### Your Membership Includes:

- A quarterly newsletter, The Wisconsin Connection
  - Discounts on trainings or conferences
  - FREE OR LOW COST social and support opportunities
  - The ability to apply for scholarships and financial help
  - Assurance that there will be a voice for all who have Prader-Willi syndrome. PWSA of WI, Inc. celebrated 26 years of reaching out to provide support, education and advocacy to persons with Prader-Willi syndrome and their loved ones across the State of WI.
  - Every year scholarships are awarded to campers who have PWS and are in need of financial assistance so they can attend summer camp.
  - Each Winter/Spring a social event is sponsored by PWSA of WI, Inc. for persons with this disability, their siblings, and those who support them. More than 100 people who have Prader-Willi syndrome attend. This is a time for making new friends, rekindling old friendships, sharing and having a great time. The unique nutritional and behavioral needs of the participants are specifically addressed.
  - Once a year, a training workshop or some other educational project is conducted that helps those who work with children and adults with PWS gain a better understanding of their needs and how to make the lives of those with Prader-Willi syndrome more successful.
  - Every day, information and support is provided to callers and others who seek help. Brochures and other printed material are shared at no cost. When requested, onsite training and consultations are conducted.
- Visit [pwsaofwi.org/Membership](http://pwsaofwi.org/Membership) to sign up!
- \$25 Single
  - \$40 Family
  - \$50 Professional
- \*Scholarships available for those who cannot afford a membership\*



# VIRTUAL BINGO BASH



On January 30th and March 13th we hosted virtual bingo nights. We were joined by approximately 30 people for each event and had a great time! Game winners each received a \$10 giftcard. It was so great seeing everyone.

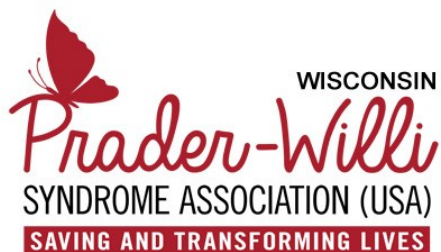
We will be hosting our next bingo night April 17th from 7-8 PM. Visit our website [pwsaofwi.org](http://pwsaofwi.org) to register.

**To purchase PWSA of WI merchandise visit [pwsaofwi.org/merchandise](http://pwsaofwi.org/merchandise)**



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**Permit #75**



|  |                    |                             |
|--|--------------------|-----------------------------|
| <b>PWSA of WI, Inc.'s Event Calendar</b> |                    |                             |
| Virtual Bingo Bash                       | April 17th, 2021   | From your own home via Zoom |
| May Awareness                            | May 1st-31st, 2021 | Info coming                 |
|  |                    |                             |