



# THE DUCT

A Monthly Newsletter for the PSC Community

August 2019

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Quote from 2019 PSC Partners Conference attendee:

*"Overall I thought the conference was terrific. (There was) an impressive line-up of speakers, and great content. The organizers did an amazing job, and the discussion sessions were very helpful."*

## PSC Partners Supports Four New Research Projects



Every year, on the recommendation of the Scientific/Medical Advisory Committee (SMAC), the Board of Directors of PSC Partners Seeking a Cure chooses the most promising research projects to support.

Research Grantees for 2019 are:

- *Jesus M. Banales, Ph.D., Head, Liver Diseases Group, Biodonostia Health Research Institute, San Sebastian, Spain:*

Metabolic-based prediction of prognosis in patients with primary sclerosing cholangitis and early diagnosis of cholangiocarcinoma: new non-invasive strategy

- *Prof. Dr. C.Y. Ponsioen, Department of Gastroenterology & Hepatology, Amsterdam University Medical Centers, Academic Medical Center.*

Single-cell RNA sequencing of lymphocyte subsets and cholangiocytes in non-endstage PSC patients

- *Lewis R. Roberts, MB ChB, PhD, Professor of Medicine and Consultant, Director, Hepatobiliary Neoplasia Clinic, Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester MN:*

Genome Wide Association Study (GWAS) in Biliary Tract Cancer (BTC)

- *Orith Waisbourd-Zinman, MD, Schneider Children's Medical Center of Israel, Felsenstein Research Medical Center, Tel-Aviv University, Sackler Faculty of Medicine, Tel-Aviv University, Tel-Aviv, Israel:*

Pathways of Injury and Repair of the Extrahepatic Biliary Tree in PSC

For more information about this research as well as updates on other PSC Partners' supported research, [click here](#).

## Quotes From PSC Partners 2019 Conference Post-Conference Survey

"This year, in particular, it was a bit awe-inspiring to hear the professionals present the progress being made and the hope moving forward. I will not forget one of the doctors describing that PSC is getting the attention that Hepatitis C did five years ago. This fact alone is incredibly hopeful and gives the dream of finding treatments and a cure clarity."



"The conference was the best thing that happened to me since my diagnosis."

"I have made hundreds of friends through the PSC Partners Conferences. Throughout the year, we reach out to each other to check in. Sometimes this is just to say hi and others it is to cry due to tough news or a hospitalization. Most importantly, we have each other to lean on as we go through the highs and lows.

We cannot run from PSC, that's a fact, so, we are stronger together as we face it."



"Being able to volunteer to help make things run smoothly and the peer sessions (were meaningful parts of the conference). Karaoke was fantastic, too, and I think it helps form community."



"It was hopeful to hear about the direction of research and the possibility of new medicines in the not-too-distant future."



"What I liked best about the conference was the hope it gave me. How can you not feel hope when a cure may be just down the road?"

"Cost was an issue for me, but, after going, I thought the value for what I received was very good. In the future, I will make this a financial priority."

***Videos and slide presentations from 2019 conference sessions will be available soon on our website. We will announce on social media when they are uploaded, and we will send out a special edition of The Duct.***



Save the Date

**16th Annual PSC Partners Conference**  
*in collaboration with University of Colorado Health*  
**April 24-26, 2020**  
**Denver, Colorado**

*More information coming soon.  
See you in the Mile High City!*

## Host the 2021 Conference



If you are interested in hosting the 2021 PSC Partners conference in your city, please complete the [Conference Host Proposal](#).

To be considered as a host, the form must be completed by October 15, 2019, so the PSC Board of Directors can choose a venue and announce the host city at the 2020 conference. If you have any questions, email us at [contactus@pscpartners.org](mailto:contactus@pscpartners.org).

## Adult PSCers Needed for

# HIGHTIDE Clinical Trial

Attention PSC patients, families, and caregivers: HighTide Therapeutics is conducting a clinical trial for PSC in the U.S. and Canada. This is their message to PSCers living in those areas:

**Re: Protocol HTD1801.PCT003 - A Proof-of-Concept and Dose-Ranging Study Investigating the Efficacy and Safety of berberine ursodeoxycholate (HTD1801) in Adult Subjects with Primary Sclerosing Cholangitis (PSC)**

HighTide Therapeutics USA are conducting a clinical trial to evaluate the safety and efficacy of berberine ursodeoxycholate (HTD1801) in 90 adults with primary sclerosing cholangitis (PSC). Berberine ursodeoxycholate is an investigational drug actively being evaluated in clinical trials for safety and efficacy in several conditions. Recruitment is actively ongoing, and is approximately half complete.

**About Berberine Ursodeoxycholate (HTD1801)**

Berberine ursodeoxycholate, previously known as HTD1801, is a salt containing two active ingredients, combined in a 1 to 1 ratio into a tablet. Thus, these two active ingredients have been combined into one new, single drug. One of the 2 main ingredients in HTD1801 is ursodeoxycholate (UDCA), which is already approved by the United States ("US") Food and Drug Administration ("FDA") as a prescription drug to treat patients with other liver diseases. The other main ingredient is berberine, a plant-derived product that can be purchased without a prescription in the US and around the world, has been used in China for over 2,000 years to help treat a variety of disorders and is even approved as a prescription drug in countries with very high regulatory standards such as Japan. Laboratory and animal data obtained by HighTide indicate that the berberine ursodeoxycholate salt yields results that are clearly superior to the simple mixture of berberine and UDCA. The specific properties of the salt provide the support for HighTide's belief that a significant new treatment is coming for patients with PSC. In September 2018, the FDA granted HighTide "Fast Track" designation for HTD1801 in the treatment of PSC, reflecting the recognition that HTD1801 has the potential to address an unmet medical need based on data shared with the FDA.

### **About the Adult PSC Clinical Trial (Protocol HTD1801.PCT003; NCT03333928)**

Protocol HTD1801.PCT003 is an 18-week long study divided into three treatment periods. In the first period, eligible subjects are randomly assigned to receive low dose, high dose, or placebo for 6 weeks. In the second period, every study participant will receive one of two doses of berberine ursodeoxycholate for 6 weeks. In the third period, half of the subjects will be randomly assigned to either continue with the low or high dose HTD1801 or be switched to a placebo for the final 6 weeks.

Even though some patients may receive placebo (an inactive comparison agent) for a part of the study, every study participant will eventually receive active berberine ursodeoxycholate. Potential study subjects do not need to stop taking UDCA to be eligible for the study, but if a patient is currently receiving UDCA, the dose and frequency should be unchanged for a minimum of 6 consecutive weeks before active study participation. Once enrolled, subjects must stop taking any previously prescribed UDCA to make sure they are not getting a "double dose" of UDCA at any time during the study. Study participants will take their other assigned study medication twice a day for a total of 18 weeks.

### **Emerging Berberine Ursodeoxycholate Clinical Data**

Emerging safety and tolerability data from recent clinical study data confirm that berberine ursodeoxycholate appears safe in the approximately 200 patients and healthy volunteers who have taken it so far in clinical trials.

### **New Investigational Centers**

Two dozen research centers in the US are currently open and enrolling patients in this study. Additional research centers have recently opened to conduct this study in the United States. New investigational centers have just been initiated in the Baltimore, Denver, and Fresno local areas. HighTide are also currently working to open investigational centers in Canada in 2019. More information on expansion of this study to Canada will be made available as regulatory activities progress.

## How Can I Get More Information?

If you are interested in possibly participating in this study, have questions, or would like help locating a participating center, please email [clinical.trials@hightidex.com](mailto:clinical.trials@hightidex.com). One of our team members will respond to you personally within 2 days.

For a complete list of medical centers conducting the berberine ursodeoxycholate clinical trial, please see the trial listing on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), or visit [www.pscclinicaltrials.com](http://www.pscclinicaltrials.com).

Thank you for your interest in our PSC study.

Best regards,

HighTide Therapeutics USA  
[clinical.trials@hightidex.com](mailto:clinical.trials@hightidex.com)  
[www.pscclinicaltrials.com](http://www.pscclinicaltrials.com)



## *Living with PSC Episode #13: PSC Partners Conference Conversations*

In this episode of Living with PSC, Niall McKay talks with various people at the 15th Annual PSC Partners Conference. Check it out [here](#).

The Living With PSC podcast series is moderated by Niall McKay. Each month, this podcast explores the latest research and knowledge about PSC. From patient stories to the latest research updates from PSC experts to collaborations that are necessary to find better treatments and a cure, this podcast has it all! Click [here](#) for a complete list of episodes as well as past PSC Partners blog posts.

## **2018 Annual Report Is Just A Click Away**

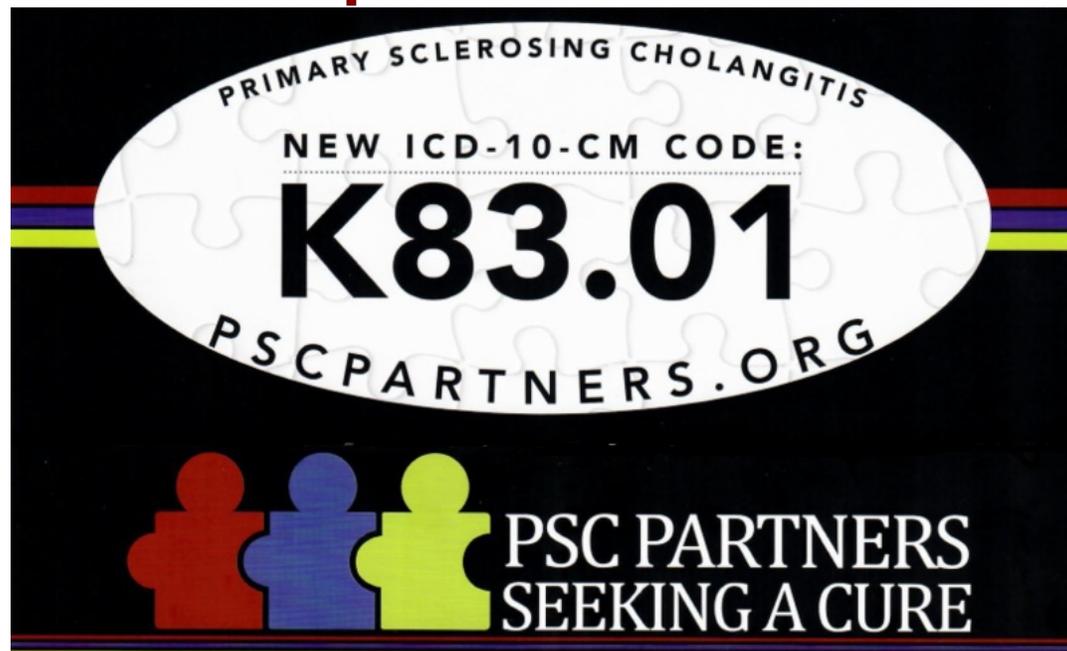
For the first time, PSC Partners Seeking a Cure has produced a traditional annual report filled with financial information, a glimpse at our history, a list of our 2018 successes, and more.



We are proud of this document, which is a visual representation of the past, present, and exciting future of the nonprofit.

[Click here](#) to view the document.

## **PSCers... Remind Your Medical Providers To Update Your Code**



This is important, because use of the code facilitates:

- Identification for trials
- Robust epidemiological and natural history studies
- Early and better identification and assessment of therapeutic outcomes, and more.

We have postcards you can take with you to your next appointment. [Click here](#) for a printable postcard, or email [contactus@pscpartners.org](mailto:contactus@pscpartners.org) to request that a postcard be mailed to you.

## *Does Your Company Support Workplace Giving?*

### **Whether You're a Federal Employee or Not, Many Companies Have Donation Programs**



Donating by payroll contribution is a great way to participate in your company's workplace giving program! Plus many companies match donations, making your contribution go twice as far.

- Are you a federal employee? We participate in the [Combined Federal Campaign](#) (CFC), and our CFC code is 79370.
- You also can support us through [United Way](#). Write in "PSC Partners Seeking a Cure" and our address, 6900 E. Belleview Ave., Ste 202, Greenwood Village, CO, 80111.
- Some companies have their own payroll deduction/matching programs. Ask your human resources department for information.

Most of these programs kick-off in the fall, so now is the time. Ask your HR representative how to enroll, or call/email PSC Partners with questions. We're also happy to work directly with your HR department.

Why not encourage your co-workers to support PSC Partners Seeking a Cure? If you need brochures, the annual report, or other documents sent, let us know. [Click here](#) for more information about supporting PSC Partners Seeking a Cure.

**PSC Contact Info: Phone: 303-771-5227**

**Email: [contactus@pscpartners.org](mailto:contactus@pscpartners.org)**

**Thanks!**

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Thanks! Happy shopping.

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*The mission of PSC Partners Seeking a Cure is to provide education and support to PSC patients, families and caregivers and raise funds to research causes, treatments and cures for primary sclerosing cholangitis.*

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