

INTERCEPT PHARMACEUTICALS INITIATES PHASE III STUDY OF OBETICHOLIC ACID (INT-747) IN PBC

Intercept Pharmaceuticals, Inc. has opened enrollment at several U.S. and European clinical trial centers for its Phase III study of obeticholic acid (OCA; previously called INT-747) in PBC. Approximately 60 centers in 12 countries are planned to participate worldwide. Sites in Canada are expected to open by July 2012.

To be eligible for the study, patients must be on a stable dose of UDCA (or unable to tolerate UDCA), must have an elevated alkaline phosphatase (AP) level of more than 1.67 times the upper limit of normal and a bilirubin level of less than 2 times the upper limit of normal. In this study, patients will receive OCA or placebo (a "sugar pill") for 12 months, then may enter a long-term study extension during which they will take OCA (free of charge) for up to 5 years. Patients who previously participated in a trial of OCA are not eligible for enrollment in this study.

Additional information about the study is available at the websites below. A list of PBC doctors participating in this study and contact information has been posted at:

- Intercept's websites: www.pbc-study.com and www.interceptpharma.com
- ClinicalTrials.gov (a registry of federally and privately supported clinical studies conducted in the United States and around the world): <http://clinicaltrials.gov/ct2/show/NCT01473524?intr=%22INT-747%22&rank=4>

PRIOR PHASE 2 STUDIES

Last year, Intercept reported that a 12 week study of OCA given alone as a monotherapy showed highly significant reductions in AP, the primary endpoint, compared with the patients receiving placebo. In 2010, Intercept reported data from a study of OCA in PBC patients who were also being treated with UDCA. The combination of the two drugs showed a significantly greater improvement in disease markers compared to UDCA alone. In both studies, pruritus (itch) was reported more commonly in the OCA-treated patients and increased with dose; otherwise, all other potential side effects were generally similar across the different treatment groups. Lower doses of OCA are being tested in the new Phase III trial, which, it is hoped, will be associated with less itch.

Additional supportive data were presented this month for the long term study extensions of OCA in PBC, showing positive results in patients who received OCA as monotherapy or in combination with UDCA for 6 months or 1 year. A small number of patients are continuing in the monotherapy study extension and may have received OCA for over 2 years, depending on when they started.





RESEARCH PARTICIPANTS NEEDED

Researchers at the University of Calgary's Faculty of Medicine are trying to study the use of Grapefruit juice in reducing the Pruritus (itchy skin) that in Primary Biliary Cirrhosis (PBC). We will do this by comparing two types of grapefruit juice to determine which is more effective in reducing pruritus associated with PBC.

Who are we looking for?

History of Pruritus, 18 years or older with established PBC and on a stable Ursodeoxycholic Acid (UDCA) dose for at least 6 months.

What will I have to do and for how long?

We are asking you to participate in a 5 week study which will involve the consumption of grapefruit juice and 5 visits to the clinic. During the visits the Dr. will examine you and carry out some tests. You will also be asked to fill out questionnaires.

Will I benefit?

You will help us determine which grapefruit preparation, if, any, will help reduce the itching associated with PBC. Participation in this study may be of no direct benefit to you. You will not receive compensation; however the study agent (grapefruit juice) will be provided to you free of charge and you will be reimbursed for parking costs during your clinic visits.

**For more information and to participate, please call: Itsabo John Oshiomogho, Clinical Research Assistant
(403) 210-6951 or jjoshom@ucalgary.ca**

ANNUAL GENERAL MEETING

The Annual General Meeting was held at 8 Covington Road, Toronto on Saturday, April 21, 2012. Nine members and one husband were present and the President held 29 proxies, surpassing the required quorum.

The meeting opened at 10:00 a.m. and official business proceeded briskly. Minutes of the previous meeting were accepted as read. The President went over the financial statement, which shows that the Society was in good financial shape at the end of 2011. The statement was accepted as presented and members voted to retain Mark Wolanski, our new and extremely professional and helpful accountant in 2012.

The President then read her report covering the activities of the Society during 2011, including communications, fundraising and research grants awarded.

Following acceptance of the President's report, the meeting approved by a show of hands the slate of officers, which remains unchanged from 2011. Regional Coordinators are also unchanged. The position of Fundraising director is still vacant, as is that of Regional Coordinator for the Greater Toronto area. Applications are welcome.

As there was no new business, the formal meeting adjourned and gave way to a lively and informal exchange of information and experiences among the members present while enjoying the refreshments provided. Thanks go to Katherine Fuerst for arranging the meeting room.

regional connections

ATLANTIC CANADA

We are enjoying heat wave. We had a temperature of 27C today (March 23), which is an all time high for this March date. They say we should sit outside for at least 15 minutes every day, so today it was an easy thing to do.

Approximately 10 of our PBC members and friends attended the annual Liveright Public Education Conference that is put on annually in conjunction with the Nova Scotia Division of the Canadian Liver Foundation. It was an excellent event with speakers on immune suppression, nutrition, liver biopsy, transplant protocol, nursing care and liver regeneration. Healthy snacks and lunch were provided and greatly enjoyed. As well, it was good to catch up on each other's news. To top things off, nine of our attendees were lucky enough to win a door prize.

Several members were unable to attend due to ill health, so we wish them a speedy recovery. To those who are away travelling, we hope you are having as great weather and as much fun as those of still here in NS.

Wednesday, May 23rd, is our annual social. We are meeting at 10 a.m. for Bingo Bowling at the Fairlanes Bowling Alley, Halifax Shopping Centre. After we've worked up an appetite, it's lunch at the food court upstairs. It's a fun game and experience is not necessary for participation. If you prefer not to bowl, please attend to cheer on our bowlers. We need someone to keep score. Hope everybody will be on tap for our next fun event.

For information about the group, please contact Judi Pemperton: atlantic@pbc-society.ca or 902-798-5554.

RÉGION DE QUÉBEC

Rencontre amicable très bientôt

Le printemps est à nos portes, le soleil est radieux. Le temps est venu d'organiser une rencontre amicale entre membres du

Groupe. Nous proposons un lunch, samedi le 26 mai. La date et l'endroit seront confirmés par courriel. BIENVENUE à toutes les personnes intéressées.

Étude sur le vécu psychologique des malades

Les membres de notre Groupe ont été invités à participer à une étude sur le vécu psychologique des malades atteints de CBP, CSP et HAI. Cette étude est menée par ALBI (France), une association pour la lutte des maladies inflammatoires du foie et des voies biliaires. Les personnes intéressées à participer à cette étude peuvent me contacter afin de recevoir les questionnaires. Les questionnaires sont uniquement en français.

Pour information contactez Francine Lamontagne: quebecrep@pbc-society.ca

QUEBEC REGION

Friendly meeting soon

Spring is upon us, the sun is shining. It is time to organize a friendly meeting between Group members. What about a lunch, Saturday, May 26th? The date and location will be confirmed by email. WELCOME to everyone.

Study on the psychological experience of patients

Members of our group were invited to participate in a study on the psychological experience of patients with PBC, PSC and AIH. The study is conducted by ALBI (France), as association to fight inflammatory diseases of the liver and biliary tract. Those interested in participating in this study can contact me to receive questionnaires. The questionnaires are in French only.

For information about the group please contact Francine Lamontagne: quebecrep@pbc-society.ca

MANITOBA

I am happy to report that the Manitoba PBC Support Group has had another gentleman join our ranks, so now we can call ourselves "The Liver Ladies and Two Lads". Four out of our group of 20 met for lunch on March 7th. We plan to get together again after Easter with hopefully greater numbers.

Since not too much has happened in our Manitoba Group, I will recount some of my personal activities. I spent several weeks in Toronto visiting my daughter, her husband and my youngest grandson, Alex, who celebrated his second birthday in February. What fun to watch a little one open gifts, eat cake and blow out candles – which had to be relit many times for repeats! (My next youngest grandson is almost 18.)

While awaiting my return flight to Winnipeg, I read an interesting article in the February 25 issue of the Toronto Star. It concerns surgery for liver cancer. Dr. Ian McGilvray is using techniques refined during liver transplantation. We are happy for advances to help those with liver disease of any type.

I am excited to be involved with my 100 Year High School Reunion taking place at the end of May. Hopefully many of my old classmates will attend. My famous brother, family entertainer Fred Penner, also graduated from Kelvin but many years later. There will be a 200 voice choir in which I plan to participate, although I may have to fake some of the high notes.

Our non-winter is almost over and I am looking forward to some gardening and enjoying the outdoors. May all of you have a great summer and continuing good health.

For information please contact Carol Seburn: manitoba@pbc-society.ca or 204-254-5226.

GOLDEN HORSESHOE CHAPTER

Seven PBC Society members and one husband met for a lovely lunch at the Lake House restaurant in Vineland on Saturday, April 14th, at 12:30 p.m. It was most enjoyable with discussion ranging from our experiences with PBC to life in general. Lunch turned into nearly three hours! We hope to meet again. This is a potential new group.



For information please contact Karen Isbister: kisbister@cogeco.ca, 905-336-3502, or Jackie Gay: gingerjack@cogeco.ca

ALBERTA NORTH



A fabulous time was had by those who attended lunch at the Cheesecake café on Saturday, March 24th. There were 16 people in attendance, including friends and family. A couple of pictures and the news from this event will be on our Facebook page.

Our next event is a BBQ at my place in Spruce Grove on Saturday, May 26th at 12 noon. Put this in your calendar! Directions and a reminder will follow closer to the event date.

For information about the group, please contact Shauna Vander Well: albertan@pbc-society.ca or 780-962-6217.

SAD NEWS

We are sorry to inform you that two long-time members of the Society, both from the Atlantic region, have died in the past little while. Wenda Lyons of Moncton, New Brunswick, died on February 16. Wenda was the talented artist who won the competition to design note cards for the Society in 2006.

Gail Pasha died on April 22 at the relatively young age of 68. Gail was last able to attend a meeting of the Atlantic group late in 2011.

FUNDRAISING

Don't forget! Sunday, June 10 is our 7th Annual Day at the Races fundraising event. There'll be a brief address by Dr. Jenny Heathcote of the Liver Clinic at Toronto Western Hospital, trackside views of exciting race finishes, a fabulous buffet, cupcakes, and a silent auction. Children and families welcome. You only have until May 31 to order your tickets. So if you are within striking distance of Woodbine Racetrack in Toronto and haven't yet done so, mark your calendar, send your order for tickets, and get set for another fun day.

CANADA HELPS

What We Do CanadaHelps is a registered charity with a goal to make giving simple. Through CanadaHelps.org, anyone can donate online to any registered Canadian charity. We have proudly facilitated over \$100 million in charitable donations through our website since it was launched in 2000.

For Donors CanadaHelps is a one-stop-shop for giving. We made donating online easy and secure.



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