

# PBC connections

A Canadian PBC Society Newsletter

2013 • VOLUME TWO

## DOUBLE-BLIND PHASE OF INTERCEPT'S PHARMACEUTICALS PHASE III TRIAL OF OBETICHOLIC ACID (OCA) IN PBC TO COMPLETE IN DECEMBER

Intercept is committed to trying to bring new therapies to PBC patients. Enrollment in the Phase III 'POISE Trial' with their drug obeticholic acid was completed at the end of 2012 with 217 patients entered in the trial across 59 centers in 13 countries. The double-blind phase of the study is scheduled to complete in December and results are expected within the first half of next year. More than 1/3 of the patients have already entered the open label long-term extension phase of the trial where they will continue to receive OCA for several years. In Canada, the study is being conducted at the University of Toronto by Dr. Hemant Shaw and at Hôpital Saint-Luc/CHUM in Montreal by Dr. Catherine Vincent.

This is an exciting time as the Phase III study with obeticholic acid (OCA) is the first time a drug has reached Phase III since Urso was developed over 20 years ago. Typically, Phase III is the last stage of a drug's development before obtaining regulatory approval. Intercept is busy with its plans and preparations toward an application for approval of OCA in PBC targeted for submission in late 2014 if the results of the POISE Trial are positive. Intercept remains in communication with the relevant regulatory authorities with plans to proceed into a confirmatory Phase 3 trial.

The long term phase of Intercept's earlier Phase II trial of OCA is currently ongoing with 19 patients continuing to receive OCA, about half of whom have been on OCA for over 3 years. Longer-term therapy with OCA continues to appear safe and tolerable in PBC patients, and the previously reported improvements in liver enzyme tests, including alkaline phosphatase, have been maintained.

More information about the ongoing Phase III POISE trial and Intercept can be found at:

- 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>
- Intercept's website: <http://www.interceptpharma.com>

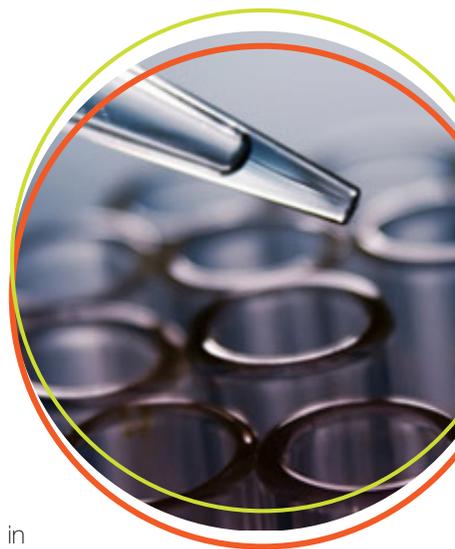
## MARK YOUR CALENDARS!

Don't miss this chance to meet **Dr. Angela Cheung**, Senior Researcher at the Francis Family Liver Clinic at Toronto Western Hospital. The Liver Clinic is one of the leading centres of research into PBC.

**Saturday, November 23, 2013 | Holiday Inn – Toronto Yorkdale | 3450 Dufferin Street, Toronto, ON M6A 2V1**  
**9:00 am – Reception and light breakfast | 10:15 am – Talk**

Please RSVP to the PBC Society by November 16: e-mail: [info@pbc-society.ca](mailto:info@pbc-society.ca) phone: 416-440-0917 toll free: 1-866-441-3643

Parking is available at the hotel (\$9) or opposite at Yorkdale Mall.



## TO ALL PBC SOCIETY MEMBERS,

First of all, I'd like to thank you for the chance to introduce myself to the PBC Society through this fantastic newsletter. I am honored to have the opportunity to care for the patients to whom Jenny Heathcote dedicated so much of her time. She truly paved the way for all PBC patients globally when she revolutionized the treatment for PBC, and as most of you probably know, she began a new journey of her own when she retired in June of this year. While I've not yet had an impact globally, I've certainly experienced medicine on a national and global scale. I began my medical training in the city where I spent most of my youth: at the University of Alberta in Edmonton. There I graduated first with a Bachelor of Science and then a medical degree. I then decided to move to Queen's University to complete the rest of my medical training before completing Gastroenterology and Hepatology training at the University of Toronto. Over the years, I developed a particular interest in Global Health, with a desire to learn more about how medicine is practiced elsewhere, and how this knowledge could be used to enrich healthcare delivery in Canada and vice versa. To that end, I've travelled to Singapore, Ethiopia, Newcastle and Brazil to learn more about medicine on a global scale. Primarily, however, my focus is in autoimmune liver disease with a research interest in understanding the population effects, patterns and the root causes of autoimmune liver disease. We have still much to learn about why PBC happens, why some have symptoms and others do not, and why some people do not respond to ursodeoxycholic acid. I hope with your help that we can begin to answer these remaining questions. If we've not met already, I look forward to meeting you in the months to come.

Sincerely,



Angela Cheung

## SAD NEWS

Kathy Ogden, a member in the Atlantic region, died on May 24, 2013. Kathy will be missed by her family and wide circle of friends. Many are not aware that she was a very talented fabric artist.

## FUNDRAISING

### ANNUAL DAY AT THE RACES

After two exceptional, record-setting years in the trackside tent, this year's Day at the Races at Woodbine Racetrack in Toronto was again held in the elegant Northern Dancer Room overlooking the finishing post. The atmosphere in the room clearly indicated a high level of satisfaction as, once more, PBC Society members, friends and family enjoyed a gourmet buffet lunch, cheered for their chosen horses, generously bid on silent auction items and bought tickets for a 50/50 draw. Betty Van Luven, our competent and vivacious MC, shared with us her experience when diagnosed with PBC and encouraged everyone to continue to support the Society. A highlight of the afternoon was a special cake marking the 10th anniversary of the Society, donated by Diana Ponti, owner-operator of Call Me Cupcake, Gourmet Cupcakes and Sweets Boutique.

Our thanks go to Diana, to Schonberg Farms for their continuing support and sponsorship of the PBC Society race, to donors of items for the silent auction, and to the always professional and helpful Woodbine Racetrack staff. Special thanks, as always, go to Barbara Badstober, for making the whole thing happen.



# regional connections

## ALBERTA NORTH

I had coffee with a new member, Laurie, on Saturday June 15. A BBQ is being held in September.

For more information, please contact **Shauna Vander Well:** [AlbertaN@pbc-society.ca](mailto:AlbertaN@pbc-society.ca) or 780-962-6217.

## ATLANTIC

*Spring Get-together:* There were only four of us who were available for our spring get-together, but we enjoyed some bingo bowling, and then had lunch. We hope that we will have a better turnout for our fall meeting and lunch.



*Fall Get-together:* We are planning our fall meeting/get-together, and have decided to try a Sunday afternoon, in the hopes that some of the people who are working will be able to attend. Sunday, October 27 at 1 p.m. is the date, and it will be held in the social room in our (Pat and Pat Berrigan's) condo at Lake Banook Woods, 30 Brookdale Crescent. It is across the street from MicMac Mall, and everyone knows how to get to the mall. We thought that we could all bring something in the line of finger foods... sandwiches, fruit platter, hors d'oeuvres, sweets, whatever you like. Coffee and tea will be provided. That way, we can mingle and have a visit together better than at a restaurant. Please let me know as soon as possible if you plan to attend. Hope to see you all on October 27.

Judi Pemberton had successful hip surgery this summer and is recovering.

For more information, please contact **Judi Pemberton:** [atlantic@pbc-society.ca](mailto:atlantic@pbc-society.ca) or 902-798-5554.

## BRITISH COLUMBIA

For more information, please contact **Kathryn Swift:** [bc@pbc-society.ca](mailto:bc@pbc-society.ca)

## GOLDEN HORSESHOE REGION

For more information, please contact: **Karen Isbister:** [kisbister@cogeco.ca](mailto:kisbister@cogeco.ca) or 905-336-3502 and **Jackie Gay:** [gingerjack@cogeco.ca](mailto:gingerjack@cogeco.ca) or 905-937-1081.

## MANITOBA

The Manitoba Support group had their last luncheon together on April 26. Since then our connection has been through email and telephone calls. Now that summer is almost officially over, fewer people will be on vacation and more likely to be free for meetings.

I shared an article from the July 29th issue of McLean's magazine entitled "Why Do We Itch?" It contains some interesting information about research into itching from many causes. It would be great to find a simple solution to this symptom of PBC! I have just this moment been notified (phone call) that the Canadian Liver Foundation will be sponsoring a meeting, to take place this fall, with a pharmacist who will discuss the problem of pruritis.

On June 14, I attended an evening of information, with a cooking demonstration and tasting of healthy "liver smart" foods. A dietitian was on hand to answer questions. Another evening like this may take place this autumn. I am hoping that more of my contacts will attend.

For more information, please contact **Carol Seburn:** [Manitoba@pbc-society.ca](mailto:Manitoba@pbc-society.ca) or 204-254-5226.

## OTTAWA

For more information, please contact **France Foucoul:** [ffoucoul@hotmail.com](mailto:ffoucoul@hotmail.com)

## QUÉBEC

For more information, please contact **Francine Lamontagne,** Représentante Québec, Société canadienne de la PBC: [quebecrep@pbc-society.ca](mailto:quebecrep@pbc-society.ca)

## SOUTHWESTERN ONTARIO

For more information, please contact **Betty Van Luven:** [bvanluven@rogers.com](mailto:bvanluven@rogers.com)