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Canada's Hepatitis C News Bulletin

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EASL CONFERENCE 2009

The EASL (European Association for the Study of the Liver) 2009 conference was held this year in Copenhagen April 22-26 2009.

This yearly conference, where trial results for new drugs, good or bad, are reported, has become one of the most important in the world. Many of our Canadian specialists attended and returned full of hope for the future of their patients. 25 new HCV drugs were presented here, including 7 protease inhibitors, 16 polymerase inhibitors, one NS5A inhibitor, plus the interferons albuferon and lambda. Also of interest were two IRES (entry inhibitors), 3 cyclophilin inhibitors, and intravenous silimarin (the "helpful" ingredient in milk thistle). NATAP has kindly sent us the reports some of which we have summarized. www.natap.org

In spite of good results shown by the "designer" drugs developed especially to attack specific areas of the Hep C virus (protease, polymerase, etc), resistance is a factor to deal with. The virus mutates rapidly. Jules Levin of NATAP believes that the future holds treatment with 2 or more oral HCV drugs combined with today's standard treatment, perhaps with improved interferons with fewer side effects at great response rates. Others hope IFN and RBV can be eliminated.

EASL: PROTEASE INHIBITORS

Jay H. Hoofnagle, M.D., discussed (*New England Journal of Medicine*, April 30) the preliminary results with protease inhibitors combined with PegIFN and RBV, which were about the same as standard treatment alone. He pointed out that the relapse rates were lower, so the SVR (sustained viral response) was improved with the addition of the protease inhibitor.

Dr. Hoofnagle reminded us of the Hep C treatment landmarks we have seen:

1. Use of interferon (IFN)
2. Addition of ribavirin (RBV or R)
3. Pegylation of interferon (2001)

…and stated, "Telaprevir, an agent developed specifically to target HCV, represents a new era of therapy for hepatitis C."

The phase 2 trials combining telaprevir (T) with peginterferon (P) and ribavirin (R) show it increases response to treatment in genotype 1 patients from about 45% to 65%, and will cut therapy to 24 rather than 48 weeks, avoiding half of the cost and many side effects.

TELAPREVIR PROVE1

(Protease Inhibition for Viral Evaluation 1)

The phase 2b trial took place from June 2006 to September 2006. 263 treatment-naïve genotype 1 patients were enrolled in the US.

SVRs (Sustained Viral Response)**:**

- 41% in the PR48 group. This is standard treatment (SOC), a control arm. The PR means pegIFN and ribavirin. "48" refers to the number of weeks it was administered.
- 35% in the T12PR12 group (A)
- 61% in the T12PR24 group (B)
- 67% in the T12PR48 group (C)

Relapse rates for groups B and C (2% and 6%, respectively) were lower than those in the control group (23%), so possibly only 24 weeks of treatment is enough for those with rapid virologic response (RVR).

7% of patients receiving telaprevir experienced breakthrough (increase in the viral load of 1 log10 or more, or an increase to over 100 IU/ml, if the virus had been undetectable.)

Side effects caused 21% to stop therapy in the telaprevir groups, vs. 11% in the SOC

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EASL: POLYMERASE INHIBITORS

R7128 phase 2b

In a previous 4-week phase 1 study conducted in 81 treatment-naive patients, R7128 showed good short-term antiviral activity with safety and tolerability comparable to standard treatment (pegIFN/RBV). Up to 88% of patients achieved undetectable viral levels with R7128, 1000mg 2x/day plus standard treatment (SOC) , compared to 18.75% treated with standard treatment alone. In genotype 2 or 3 non-responders, results with R7128 1500mg 2x/day plus standard treatment resulted in 90% of patients achieving undetectable viral levels after 4 weeks, compared to 60% with standard treatment.

The phase 2b trial will enroll about 400 treatment-naïve genotype 1 or 4 patients, and combine R7128 with standard treatment in an attempt to improve SVR and shorten treatment time. The trial will be held in North America, Europe and Australia. Patients will be enrolled in one of 5 arms:

- R7128 500mg 2x/day with SOC for 12 wks, then 12 wks SOC (12+12)
- R7128 1000mg 2x/day with SOC for 12 wks, then 12 wks SOC (12+12)
- R7128 1000mg 2x/day in combination with SOC for 8 wks, followed by 16 wks of SOC (8+16)
- R7128 1000mg 2x/day with PEGASYS SOC for 12 wks, followed by 36 wks SOC (12+36)
- A control arm with SOC for 48 wks.

Patients in the 24-week arms will discontinue all treatment at week 24 if they have achieved RVR, defined as undetectable levels of HCV at week 4 (a strategy known as "RVR-guided" treatment), and maintain undetectable levels of HCV until week 22. Patients who do not achieve an RVR at week 4 will continue on SOC until week 48.

Filibuvir (FBV-formerly PF 00868554)

35 treatment-naive, mostly genotype 1a subjects received FBV (200, 300 or 500 mg

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The *hepc.bull* welcomes and encourages letters to the editor. When writing to us, please let us know if you do not want your letter and/or name to appear in the bulletin.

FAQ version 8.1

Peppermint Patti's FAQ Version 8.1 is NOW AVAILABLE, Version 8 is available in FRENCH and Version 7.1 is available in SPANISH. The ENGLISH version includes the latest treatment information and research from 2008. Place your orders now. Over 140 pages of information for only $12 each. Contact HepCBC at (250) 595-3892 or info@hepcbc.ca

HepCBC Resource CD

The CD contains back issues of the *hepc.bull* from 1997-2007; the FAQ V8; the slide presentations developed by Alan Franciscus; and all of HepCBC's pamphlets. The Resource CD costs $10, including S&H. Please send cheque or money order to the address on the subscription/order form on this page.

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THANKS!!

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Please patronize the following businesses that have helped us: Top Shelf Bookkeeping, Thrifty Foods, Samuel's Restaurant, Margison Bros. Printers, Roche Canada, VanCity, Schering Canada, Shoppers Drug Mart, and the Victoria Conservatory. Heartfelt thanks to Blackwell Science for a subscription renewal to gastrohep.com.

CUPID'S CORNER

This column is a response to requests for a personal classified section in our news bulletin. Here is how it works:

To place an ad, write it up! Max. 50 words. Deadline is the 15th of each month and the ad will run for two months. We'd like a $10 donation, if you can afford it. Send a cheque payable to **HepCBC,** and mail to **HepCBC, Attn. Joan, #306-620 View Street, Victoria, BC V8W 1J6, (250) 595-3892.** Give us your name, tel. number, and address.

To respond to an ad: Place your written response in a separate, sealed envelope with nothing on it but the number from the top left corner of the ad to which you are responding. Put that envelope inside a second one, along with your cheque for a donation of $2, if you can afford it. Mail to the address above.

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PRE-PLANNING YOUR FINAL ARRANGEMENTS?

Please consider arranging for donations to your local hepatitis C organization.

EASL:THE PROTEASE/ POLYMERASE COMBO

INFORM-1

Probably the most exciting news at the conference was the report from the study combining two oral HCV drugs—a milestone in HCV drug development.

The phase I INFORM-1 study enrolled 57 treatment-naïve patients in Australia and New Zealand, combining ITMN-191 (AKA R7227) with the polymerase inhibitor R7128. More cohorts (arms) were added for non-responders and null responders, for twice a day dosing, and for higher doses of ITMN-191. It is especially unusual because it does not include interferon.

Results from the first 4 cohorts showed the combination is safe and effective, even without IFN, in treatment-naive HCV patients.

The original INFORM-1 protocol consists of four dosage cohorts—A, B, C and D—with a total of six dosing groups:

- Cohort A consists of two dosing groups, Group A and Group B. Group A patients take 500mg 2x/day of R7128 alone for 3 days, then combine it for 4 days with 100mg every 8 hours of ITMN-191. Group B patients take 100mg every 8 hours of ITMN-191 alone for three days and then 4 days combined with 500mg 2x/day of R7128.
- Cohort B patients (Group C) receive the same doses of R7128 and ITMN-191 as in Cohort A, but for 14 days in combination.
- Cohort C has two dosing groups: Group D and Group E. Group D patients take 1000 mg twice daily of R7128 and 100mg of ITMN-191 every 8 hours. Group E patients receive 500mg twice daily of R7128 and 200mg every 8 hours of ITMN-191.
- Cohort D (Group F) patients take 1000mg twice daily of R7128 and 200mg of ITMN-191 every 8 hours.

The new design includes three more dosage cohorts, as follows:

-Cohort E: Treatment-experienced genotype 1 patients take the combination of ITMN-191 (600mg) and R7128 (1000mg), or placebo, twice-daily.

-Cohort F: Null-responder genotype 1 patients. Null response is having less than a 2.0 log10 drop in RNA at week 12, and/or less than a 1.0 log10 decline at week 4. Patients take ITMN-191 (900mg) plus R7128 (1000mg), or placebo, twice daily.

-Cohort G: Treatment-naive patients take the combo twice-daily of ITMN-191 (900mg) and R7128 (1000mg), or placebo.

Patients receiving the combination of R7227 and R7128 for 14 days—without pegIFN or RBV—had an average drop in viral levels of 4.8 to 5.2 log10 IU/mL with the highest doses. Adding R7128 to R7227 resulted in 63% of patients dropping to undetectable. 25% in the highest dosage groups tested undetectable at 14 days.

EASL: NEW DRUGS

DEBIO 025

Debio 025 is a cyclophilin inhibitor. Cyclophilins are important for HCV replication. A previous study showed that Debio 025, taken orally by itself twice daily over 15 days caused an average 3.6 log10 drop in viral load in HIV/HCV coinfected patients. It was effective for genotypes 1, 3 and 4.

This later 29-day trial enrolled 86 treatment-naïve patients, genotypes 1-4, which combined the product with pegIFN. (The doses were lower than their previous monotherapy trial.) The most impressive average responses were in the higher two doses of Debio 025 plus pegIFN-a2a. 4 subjects dropped out due to elevated bilirubin levels which were reversible. After 4 weeks of treatment, the mean viral load was below detectable levels. Among the genotypes 1 and 4 patients, 8 out of 12 in the high-dose group had undetectable HCV. No resistance or rebound was seen. (Note: Ribavirin was not used.)

NITAZOXANIDE

The phase 2 trial in treatment-naïve genotype 1 patients combining Nitazoxanide (NTZ) with standard treatment (SOC) resulted in an 80% EVR vs 68% for standard care. In subjects with a high viral load, the EVR results were 79% vs 61%. Another phase 2 trial with NTZ plus SOC is studying non-responders. The results from week 28 were released and showed that 14% of those taking NTZ+SOC had undetectable HCV, compared to 5% on SOC only.

PSI-7851

PSI-7851, a polymerase inhibitor, has shown anti-HCV activity more potent than R7128 against all of the most common HCV genotypes. A phase 1 trial began in March with healthy volunteers. First results are expected later this year.

GS-9450

GS-9450 has been proven a very potent caspase inhibitor in pre-clinical trials. It was administered orally in healthy volunteers in single and multiple doses to test the safety in humans. It was well tolerated up to 120 mg in men and 40 mg in women. Phase 2 trials are underway in patients with HCV.

NOW ENROLLING HEAT Study (HCC)

HEAT Study
Hepatocellular Carcinoma of RFA and ThermoDox®
Now Enrolling Recently Diagnosed Hepatocellular Carcinoma (HCC) Patients in Clinical Trials

Celsion Corporation is an oncology drug development company which develops targeted chemotherapeutic treatments based on a unique heat-activated liposomal technology. Celsion is currently enrolling patients in a global Phase III clinical trial – the HEAT Study–which is designed to demonstrate the safety and efficacy of ThermoDox® in hepatocellular carcinoma (HCC) patients.

The HEAT study involves an investigational anti-cancer drug, called ThermoDox®, used in combination with an approved medical device for radiofrequency ablation (RFA) in the liver.

The study will be the largest investigation of RFA in HCC and will involve approximately 600 patients in over 40 research institutions in seven countries and regions.

ThermoDox is designed as a heat-activated liposomal technology that is administered intravenously. When used in combination with RFA to ablate tumors high concentrations of doxorubicin is released directly to the tumor and the surrounding liver tissue. The primary endpoint of the trial is progression-free survival.

For more info, contact:
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The clinicaltrials.gov link for this trial is:
www.clinicaltrials.gov/ct2/show/NCT00617981?term=celsion&rank=6

WARNING

On May 1, the US FDA sent a warning to immediately stop using **HYDROXYCUT**, dietary supplements sold for weight loss, etc., also sold under the names **IOVATE** and **MUSCLETECH**. There have been 23 reports of important problems, including liver injury requiring transplant and death from liver failure. There is an ongoing investigation.

www.fda.gov/medwatch/safety/2009/safety09.htm#Hydroxycut

EASL: INTERFERONS & RIBAVIRINS

PEG-INTERFERON LAMBDA-1A

Bristol-Myers Squibb and ZymoGenetics have a product called Interferon Lambda-1a, which has now been pegylated (pegIFN Lambda). It is a type III IFN, and it is hoped it will be less toxic than the types presently used in HCV therapy. This small phase 1b, ongoing trial has enrolled genotype 1 treatment relapsers, taking pegIFN Lambda weekly or every 2 weeks, with or without ribavirin, for 4 weeks. The drug is well-tolerated and the effects are comparable to standard therapy. Half of the patients treated weekly with IFN alone had an undetectable viral load at 4 weeks (RVR). 80% had a viral load below 1000 IU/L. There were reversible increases in liver enzymes and bilirubin. There was no neutropenia. Weekly dosing was more effective, with all patients achieving a viral load drop of over 2 log10. More data is expected. The next step is a Phase 2 trial in treatment-naïve subjects.

VIRAFERONPEG

This drug produced by Schering is now approved in India for relapsers and non-responders, as a result of their EPIC3 clinical study showing that certain non-responders even to prior pegylated treatments have successful re-treatment results. 1,336 patients were treated in the study. Of those who had undetectable virus at week 12 (EVR), which according to the rules of the study, qualified them to continue treatment for a total of 48 weeks, 57% achieved SVR in the non-pegylated arm and 47% in the pegylated arm.

TARIBAVIRIN vs RIBAVIRIN

Taribavirin (TBV) is an oral drug similar to ribavirin (RBV). In this phase 2b ongoing study, 278 treatment-naïve genotype 1 patients were treated with pegIFN and either TBV or RBV for 48 weeks. Previous studies showed TBV to cause less anemia. This study investigated the efficacy of TBV compared to RBV. All adverse events were similar except the TBV patients had twice as much diarrhea, but it was mild and didn't affect the dose. TBV and RBV were shown to be comparable in viral drops and tolerability, even though the study enrolled more of the harder-to-treat groups of African-American and Latino patients than other studies (30%). TBV had notably lower rates of anemia. "These data suggest that WBD with TBV may provide a safe and effective alternative to RBV for the treatment of chronic hepatitis C."

EASL: TREATMENT TIPS

EARLY TREATMENT MORE EFFECTIVE

Patients with little or no fibrosis (scarring) respond better to standard treatment than those with advanced fibrosis. Since response rates are higher in patients with little liver damage, early treatment has better success. For patients with stage 0-2 cirrhosis, there may be an advantage by using high (induction) dose before starting standard therapy. Poor drug metabolism in the liver may explain worse response among cirrhotics.

RETREATMENT: WHO WILL RESPOND?

"57% of patients with undetectable HCV RNA at week 12 achieved an SVR in the extended treatment arms. This suggests that it is possible to identify patients most likely to achieve an SVR before treatment."

The factors indicating treatment success included a viral load less than 800,000 IU/ml, age under 45 years, body weight under 75 kg, no cirrhosis, and a genotype other than 1.

About 65% of previous non-responders with these characteristics and a viral response at week 12 were able to achieve an SVR (sustained viral response or "cure") after 72 weeks of treatment, rather than the usual 48 weeks.

72 WEEKS?

Another study presented a proposition for the treatment of genotype 1 or 4 patients: Patients with RVR (undetectable at 4 weeks) should have 24 weeks of treatment; patients without RVR but with EVR (more than 2-log drop in viral load and/or a viral load less than 50 IU/mL at week 12) should be treated for 48 weeks; patients with EVR but with a week-12 viral load of more that 50 IU/mL should continue for 72 weeks; patients who don't have EVR should not receive further treatment. Their chance of responding is less than 5%. Patients with EVR with still detectable virus had a 77% SVR rate when treated for 72 weeks compared to 37% of those treated for 48 weeks.

HIGH DOSE UDCA FOR FATTY LIVER

There is no proven therapy for fatty liver. This trial gave 30 mg per kg of weight each day of UDCA (ursodeoxycholic acid) or placebo to 126 patients with non-alcoholic steatosis, (NASH or fatty liver) and ALT levels over 50 IU/L to see if it was safe. The treatment lasted 12 months. The goal was a lower ALT, indicating less inflammation. ALT decreased an average of 55% with UDCA, and 35% with placebo. Average AST and GST decreased 59% with UDCA, and increased with placebo. The UDCA group reported more diarrhea, pain in the abdomen, and gastrointestinal problems than the non-UDCA group, but also reported improvement in strength and less right upper quadrant pain.

ROSIGLITAZONE FOR NASH

Previous short trials of glitazones had controversial biopsy results. Researchers hoped for better results with longer treatment, and re-enrolled 53 patients who had completed the FLIRT trial, which was 1 year of Rosiglitazone (RSG) or placebo. They were enrolled in two more years of treatment, all with RSG. 40 finished and were biopsied for a 3rd time. In the placebo/RSG group, steatosis (fatty liver) decreased by an average of 15% and in the RSG/RSG group, there was a 20% reduction of steatosis only in the first year. Fibrosis did not change. Researchers concluded that RSG has a good effect on steatosis during the first year, but no benefit after that, other than maintaining a good effect on insulin and liver enzyme levels.

LOW-DOSE MAINTENANCE

"The HALT-C trial demonstrated that prolonged low-dose PEG IFN therapy can not reduce the occurrence of clinical outcomes in a large population of patients with non-cirrhotic fibrosis or cirrhosis who had an initial non-response to antiviral standard therapy."

The large EPIC maintenance trial with low-dose pegIFN alfa-2b in cirrhotic non-responders to standard therapy concluded that long-term, low-dose therapy with pegIFN alfa-2b does not prevent HCC (hepatocellular carcinoma or liver cancer) in cirrhotics. It may, however, be beneficial for those with cirrhosis and portal hypertension.

—-

So what can you do if you can't get rid of the virus? Watch your weight. Control any diabetes. Don't drink or smoke. Drink coffee, but in moderation. If you can't wait for the newer treatments, consider 72-week therapy.

(**POLYMERASE**—*Continued from page 1)*

2x/day) or placebo plus SOC for 4 weeks. Patients are continuing on SOC for 44 more weeks. Results from the week 4 analysis were presented at the conference. Side effects were headache, fatigue, insomnia and nausea, and didn't seem dose-dependent. Elevated creatinine occurred in one subject in the FBV 300 mg group, which resolved with IV hydration.

RVR (Rapid Viral Response—undetectable at week 4):

0% with placebo
60% with 200mg 2x/day
75% with 300mg 2x/day
63% with 500mg 2x/day

(Continued on page 5)

(**EASL: POLYMERASE**—*Continued from page 4)*

BI 207127

The phase 1b trial enrolled 48 genotype-1 patients with mild fibrosis, who were treated orally with 100, 200, 400 or 800mg of BI 207127 every 8 hours over 5 days. All were followed for 10–14 days. 13 of the patients were treatment naïve. BI 207127 was safe and mostly well tolerated. A moderate drug-related skin inflammation was managed easily, and no dose reduction or discontinuation was needed.

In the 800mg group, 5 of 9 patients showed more than 4 log10 viral load drop, which lasted at least 24 hours after the last dose was taken. There were no cases of breakthrough. No response was seen with the placebo. Viral load drops of more than or equal to 2 log10 were achieved in most of patients receiving doses of 400mg or 800mg every 8 hours. Lab results varied little from baseline. Investigators judged tolerability of BI 207127 as good in 88% of treated patients. A trial with 1,200mg is ongoing, and a 4-week combination study will begin in late 2009.

VCH-916

VCH-916 dosing produced a rapid drop in viral load with an average decrease of 0.6, 1.5, 1.5 and 1.5 log10 over 3 days of treatment, with doses of 100 or 200mg 3x/day, and 300 or 400mg 2x/day, respectively. Breakthroughs in some subjects were associated with the presence of polymerase mutations and some of these persisted through day 140 of the trial. This study indicates that monotherapy with VCH-916 will result in HCV polymerase mutations and that combination therapy is probably necessary.

VCH-222

VCH-222 was given to healthy volunteers in single oral doses and tolerated well up to 1500mg. In HCV patients, it was well tolerated up to 750mg twice daily over 3 days.

All patients experienced more than a 3 log10 reduction in viral load after 24 hrs of treatment. An average reduction of 3.7 log10 in HCV RNA was seen after 3 days of treatment at 750mg 2x/day. No rebound of viral load was seen during treatment.

A phase 2 study has begun to determine the best dosing regimen for the drug.

ABT-333 in healthy volunteers

ABT-333 was safe and well tolerated at single, ascending doses up to 2000mg. The anti-viral potency of single ascending doses up to 1200mg was dose proportional, and not affected by food. The most common side effects were nausea, abdominal discomfort and headache. Adverse events or laboratory abnormalities weren't associated with the dose, and were mostly mild. There were no ECG changes.

IDX184 in healthy volunteers

IDX184 seemed to be safe and easily tolerated in healthy volunteers in single doses up to 100mg.

Previous studies in HCV-infected chimpanzees showed viral load reduction. There is an ongoing study which has enrolled treatment-naïve genotype 1 subjects, who are taking 25, 50, 75 and 100mg of IDX184 daily. We look forward to the results.

There are other protease inhibitors in preclinical development such as ABT-072 and IDX375. These are exciting times!

EASL: VACCINES

ChronVac

In Stockholm, 12 treatment-naïve genotype 1 patients took part in a first clinical trial of a therapeutic naked DNA T-cell vaccine, ChronVac. They were divided into groups and given an injection to deliver HCV DNA into the deltoid muscle—167 B5g, 500 B5g or 1,5000 B5g—followed by two 60ms electrical pulses, in a process called "electroporation". The electrical pulse makes the membrane of the cell more porous and stimulates migration of the immune cells. The same procedure was repeated a total of 4 times, once a month. There were no severe side effects. No patient in the first group had a reduced viral load, but two had a slight T cell response. In group 2, two patients had better T-cell responses and a viral load drop of 0.80 log10 and 1.5 log10. In the third group, one had an HCV T-cell response. Two had viral load drops of 1.2 log10 and 2.4 log10. The four patients' viral load drops lasted 2 to over 10 weeks. A phase 1/2a trial is underway.

GI-5005

The GI-5005 Phase 2 trial enrolled 140 genotype 1 patients. 74% were treatment-naïve. GI-5005 is designed to cause HCV-specific T-cell responses to help the body clear the virus. Patients received standard therapy (SOC) with or without GI-5005. GI-5005 was injected subcutaneously once a week for five weeks, then once every 2 weeks, for a total of 12 weeks, followed by SOC plus monthly injections of GI-5005 for 48 weeks. The EVR in naïve patients was 94%. That is about a 10% improvement over SOC. RVRs were twice as frequent with triple therapy than SOC. There were no serious side effects related to GI-5005. Also, blood tests indicating fibrosis (Fibrotest) and necrosis (Actitest) showed a 14% advantage with the triple therapy over SOC. The trial has not finished yet.

PegCARE

PegCARE is a reimbursement program to help people who have been prescribed Pegetron and need assistance with any co-payment they might have, whether through their provincial coverage (i.e., Pharmacare) deductible or their 3rd-party health insurance. It is pro-rated, so the less the family income is, the more help they get. If someone's net family income is less than $30,000, they will get 100% reimbursement. The income maximum is $100,000. Patients must be signed up for Fair Pharmacare to qualify, and they need to provide a copy of last year's T4 form.

There is a 24/7 Nursing Hotline and bilingual assistance available, at no charge. Other services are access to live translation services (150 languages) and injection assistance from registered nurses. Patients starting on Pegetron should ask their doctor or nurse to enroll them in PegCARE. It's an easy single-page form to fill out, which they will provide. PegCARE: 1-866-872-5773

PEGASSIST

The PegAssist Reimbursement Assistance Program provides reimbursement coordination assistance for patients who have been prescribed Pegasys or Pegasys RBV. The program will assist in securing funding for patients to ensure that they can start, stay on, and complete their treatment successfully.

PegAssist Reimbursement Specialists are available (Monday to Friday, 10 AM- 6 PM EST) by calling: 1-877-PEGASYS or 1-877-734-2797. Patients can also obtain a program enrollment form from their nurse/physician to gain access to the program.

The program provides financial aid to qualified patients, alleviating any financial barriers which may prevent patients from starting treatment, i.e., deductibles and/or co-payments.

In partnership with CALEA Pharmacy, the program can conveniently deliver the medication directly to patients' homes or to the clinics.

COMPETITION!

HepCBC is looking for writers for the next issue of the *hepc.bull*, and is willing to pay $50.00 for a featured article. The article should be original, consist of 500 to 800 words, and of course, be about hepatitis C. It may be, for example, about the author's experience with hepatitis C, a study (with references) on some aspect of the disease, or a call for action. Submissions should be in by the 15th of next month, ***stating interest in the bonus.*** If there is more than one submission chosen, the editors reserve the right to print both, or leave one for a future edition. info@hepcbc.ca

EFT TAPPING FOR LIFE'S CURVED BALLS

by Karen Hodson, BA, EFT-ADV EFT Practitioner

This is a regular segment of a series on using EFT (Emotional Freedom Techniques) to create more personal peace in a rapidly changing world.

EFT is a great tool that releases stress and often frustrating emotions when life throws you a curve ball in everyday life. It is easy to use and very handy when something comes up when least expected.

I was planning a trip and decided to get some minor maintenance on my car as a safety precaution. I was in a bit of a hurry and had not yet completed packing my things and was planning to catch a ferry. I called up my mechanic and explained what I wanted done and was assured that it could be completed quickly if I brought it in right away. I had assumed it was going to be a speedy in-out and would not cost much, either.

The mechanic did a quick overview and noted that there were some additional items that he strongly suggested that I have done. He said it would take another hour to complete and the price tag was over $400 that I had not budgeted for. Hmmm. After I got over the initial shock, I thought again about safety and that it would eventually have to get done, so I bit the bullet and agreed to proceed.

Then I went outside and tapped on all the emotional triggers that just got hit: Why was this happening?; I didn't budget for this; The delays in my detailed travel plans; Disappointment; Frustration, and all the other emotions that came up. Once I calmed down with the EFT tapping, I could then start to see more positive things and other ways of looking at the situation: There will be another ferry; I can easily pack quickly; It's providing me safety and security; A maintained car gives me freedom from worry; What if I repaired it just in time?; What if it saved my life?

Besides all of that, it gave me the opportunity to slow down from my rush and enjoy the afternoon sunshine. I sat in a sunbeam and worked on an outline for this article while being serenaded by some songbirds. In the moment I was able to tap away the frustration and emotional triggers of my plans being derailed and move into a creative, peaceful and even productive space. Normally my triggers would have carried on ranting for hours, but with the EFT tapping I dissipated the energy. I was able to let go of the story that was spinning around and around in my mind and move towards inner peace.

Here is what an EFT tapping session on dealing with life's curve balls would look like: (*See www.pivotpoint4u.com for tapping points and a full description of how EFT works*)

Tap the Karate Chop (side of the hand) the Set-up Phrase (repeated up to 3 times) then the Tapping Phrase Sequence (top of head, eyebrow, side of eye, under eye, under nose, chin, collar bone, under arm, liver point) and repeat for as many rounds as needed, adding new words or phrases as they come up, until a more balanced feeling is present. Once neutralized, go onto the next set-up and tapping phrase.

Karate Chop Set-up:
"Even though I am upset that my plans have been derailed, I deeply and completely love and accept myself."

Tapping a phrase on each point:
This frustration; My plans are ruined; Why does this always happen to me?; I feel so angry; I am so disappointed; I can't let go; I didn't expect this bad news; Things never go as planned; It just never ends.

Karate Chop Set-up:
"Even though I don't have the money budgeted for this unexpected bill, I deeply and profoundly love and respect myself anyway."

Tapping a phrase on each point:
This is not in my budget; What if I fixed it just in time? I feel so frustrated; I choose to release these frustrating thoughts; I am so angry; What if this helped save my life? All these old stories that no longer work; I choose to create new positive stories.

These sequences can be repeated for as many rounds as needed. Once a more neutral feeling is present, the following positive phrases can be introduced until it feels complete.

Tapping a Positive Phrase on each point:
I choose to trust in a positive outcome; I allow even more new money in to replace what went out; I love this peaceful feeling of letting go; It feels so wonderful to bask in the light; I love this feeling of freedom; I trust in the goodness that flows to me; I love this feeling of serenity; I choose positive thoughts; I create peace within me.

EFT tapping is a great tool to help deal with the little incidents that come up in life. It is those curve balls that life throws at you that can be challenging, but you can move through them, it makes life interesting and gives us opportunities to grow and evolve to deeper levels within us. And the ferry I was hurrying to catch on my trip…. missed it by one car (sigh). Oh, well. There was another one in two hours… tap, tap, tap.

Karen is an EFT Practitioner in West Vancouver and is offering a reduced fee for EFT sessions to people with hepatitis. You must mention this article, some restrictions apply and sessions can be over the phone. Karen would love to hear from you, please e-mail any comments or feedback. For more information: (604) 913-3060 pivotpoint4u@gmail.com

(**EASL: PROTEASE**—*Continued from page 1)*
group. Black patients in this study had an encouraging 44% rate of SVR in the telaprevir-based groups.

PROVE2, also a phase 2b trial, studied telaprevir in 334 treatment-naïve genotype 1 subjects in Europe from August 2, 2006 to January 17, 2007.

SVRs:
- 46% in the PR48 (control) group
- 36% in the T12P12 group
- 60% in the T12PR12 group
- 69% in the T12PR24 group

Response rates were lowest in the group without ribavirin. Relapse rates were 14% in the T12PR24 group and 30% in the T12PR12 group. Breakthrough was 1% in the T12PR12 group and 5% in the T12PR24 group. 7% in the telaprevir groups stopped treatment because of rashes.

PROVE3 was a phase 2 study of telaprevir in 453 treatment-experienced genotype 1 patients in the US, Canada and Europe.

Treatment regimens:
A. T12/PR24
B. T24/PR48
C. T24/P24
D. PR48 the control arm

Among previous non-responders, SVR rates were 39% group A, 38% group B, 10% group C, and 9% group D.

Among prior relapsers, the SVR rates were 69% group A, 76% group B, 42% Group C, and 20% group D.

Among subjects with prior HCV breakthrough during treatment, the rates were 57% group A, 50% group B, 36% group C, and 40% group D.

Side effects were worse with telaprevir. 48-wks of treatment including PR looks more effective for treatment-experienced patients.

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(**EASL: PROTEASE** —*Continued from page 6)*

EASL's **Study C209,** a phase 2a trial of telaprevir enrolling 49 treatment-naïve genotype 2 and 3 subjects, reported preliminary results at 2 weeks showing no real benefit for genotype 3 patients, while genotype 2 patients had an encouraging average 4 log viral load drop at about day 6. No serious adverse events were reported.

ITMN-191

In a previous phase I study, ITMN-191 reduced viral load an average of 3.8 logs as monotherapy for 14 days in treatment-naive genotype 1 patients.

ITMN-191 or placebo was tested in combination with pegIFN alfa-2a and RBV for 14 days.

HCV RNA was undetectable in most of ITMN-191 treated patients in all dosing arms at day 15. No viral rebound was seen during treatment.

SCH-900518

Schering's SCH 900518 was given to 40 genotype 1 treatment-naïve and experienced subjects, alone or combined with pegIntron. The patients took SCH-900518 alone first for 7 days, then waited 4 weeks before adding 14 days of pegIntron to the SCH 900518. Afterwards, all were given SOC.

Many of both treatment-experienced and naïve patients' viral load dropped below 25 IU/mL during combination therapy with PegIntron (with or without ritonavir) on day 15. SCH 900518 alone or combined with pegIFN was found to be safe. Good drops in viral load were achieved.

Boceprevir: HCV SPRINT-1 phase 2

Schering's Boceprevir plus PegIFN a-2b/ribavirin was given to genotype 1 treatment-naive patients .

SVRs:

•38% PR48. (control group) 86% with EVR had SVR; 100% with RVR had SVR

•54% PR/B28. 74% with RVR had SVR; 68% with EVR had SVR)

•56% PR 4 weeks lead-in then PR/B24. 82% with RVR had SVR; 68% with EVR had SVR

•67% PR/B48. 84% with RVR had SVR; 84% with EVR had SVR.

•75% P/R 4 weeks lead-in, then PR/B44. 94% with RVR had SVR; 91% with EVR had SVR.

SVR with low-dose RBV:

•36% PR/B 48 weeks

SVR could be predicted based on response during the 4 week lead-in with PR. For non-responders (less than a 0.5 log reduction), 29% taking PR for 4 wks + PR/B 24 wks had SVR, and 44% taking PR for 4 wks + PRB for 44 wks had SVR.

Patients with anemia had 88% SVR. EPO (epoetin) was used in this trial to control anemia.

Relapse: 24% relapsed in PR control group (48 weeks). The lowest relapse rate was 3% in the PR 4 wk lead-in + 44 wks PR/B group.

Breakthrough was lower in the lead-in groups: 4% with lead-in + PR/B 24 weeks.

TMC435

OPERA-1 is a phase IIa trial to assess TMC435 with PegIFN and RBV in genotype-1 treatment-naïve and treatment-experienced patients.

In arm 4, 37 treatment-experienced genotype 1 patients received either TMC435 75mg, 150mg, 200mg, or placebo daily, combined with PR for 28 days, followed by PR48 alone (total treatment = 48 weeks). Average decreases in viral load were 4.3, 5.5 and 5.3 log10 IU/mL for the TMC435 75, 150 and 200mg daily groups, respectively, at Day 28, compared with 1.5 log10 IU/mL in the placebo group.

Three viral breakthroughs were observed, all in genotype 1b patients. Side effects caused no discontinuations. Mild and reversible bilirubin elevations were observed mostly with the 200mg dose. The drug was also given to 50 treatment-naïve genotype 1 subjects who received 25, 75 and 200mg daily or placebo for 7 days. At week 12 all patients receiving 200mg + PR had undetectable viral loads. There were no discontinuations due to adverse events.

MK-7009

This ongoing phase 2a study of MK-7009 for 28 days combines it with SOC in treatment-naive patients with genotype 1. 95 treatment-naïve patients took a placebo or SOC plus 300mg 2X/day, 600mg 2x/day, 600mg/day, or 800mg/day of MK-7009 for 28 days. All patients continued SOC for 44 weeks more.

RVR rates in the MK-7009 arms ranged from 69% to 82% vs. 6% of the control group. All of the MK-7009 results were superior to the control arm. More than 80% treated with MK-7009 had undetectable virus on day 28. 77% to 94% were still undetectable on day 42. All subjects in the 600mg/2x daily group tested undetectable days 21 through 42.

MK-7009 showed no adverse events causing discontinuation. Vomiting appeared in 600mg 2x/day dose group. Virologic failure was seen in 300mg 2x/day and 800mg daily groups, with HCV mutations conferring resistance to MK-7009. Nausea and vomiting looked higher in the MK-7009 treatment groups.

Among protease inhibitors still in pre-clinical development are **AVL-181, EA-058, EA-063, IDX136 and IDX316**. Stay tuned!

COMPENSATION

LAW FIRMS

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Bruce Lemer/Grant Kovacs Norell
Vancouver, BC
Phone: 1-604-609-6699
Fax: 1-604-609-6688

Pre-1986/ Post-1990

Klein Lyons
Vancouver, BC 1-604-874-7171,
1-800-468-4466, Fax 1-604-874-7180
www.kleinlyons.com/class/settled/hepc/

David Harvey
Lauzon Belanger S.E.N.C. (Quebec)
Toronto, ON
Phone 416-362-1989; Fax 416-362-6204
www.lauzonbelanger.qc.ca/cms/index.php?page=108

Roy Elliot
Roy Elliott Kim O'Connor LLP.
hepc@reko.ca www.reko.ca/html/hepatitisc.html

Kolthammer Batchelor & Laidlaw LLP
#208, 11062 – 156 Street,
Edmonton, AB T5P-4M8
Tel: 780-489-5003 Fax: 780-486-2107
kkoltham@telusplanet.net

Other:

William Dermody/Dempster, Dermody, Riley & Buntain
Hamilton, ON L8N 3Z1 1-905-572-6688

LOOKBACK/TRACEBACK

Canadian Blood Services Lookback/Traceback & Info Line: 1-888-462-4056
Lookback Programs, Canada: 1-800-668-2866
Canadian Blood Services, Vancouver, BC
1-888-332-5663 (local 3467) or 604-707-3467
Lookback Programs, BC: 1-888-770-4800
Hema-Quebec Lookback/Traceback & Info Line: 1-888-666-4362
Manitoba Traceback: 1-866-357-0196
Canadian Blood Services, Ontario
1-800-701-7803 ext 4480 (Irene)
Irene.dines@Blood.ca

RCMP Blood Probe Task Force TIPS Hotline
1-888-530-1111 or 1-905-953-7388
Mon-Fri 7 AM-10 PM EST
345 Harry Walker Parkway, South Newmarket, ON L3Y 8P6 Fax: 1-905-953-7747

CLASS ACTION/ COMPENSATION

Class Action Suit Hotline: 1-800-229-5323 ext. 8296
Health Canada Compensation Line: 1-888-780-1111
Red Cross Compensation pre-86/post-90 Registration: 1-888-840-5764

Ontario Compensation: 1-877-222-4977
Quebec Compensation: 1-888-840-5764
http://www.phac-aspc.gc.ca/hepc/comp-indem_e.html

CLAIMS ADMINISTRATOR

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Administrator 1-877- 434-0944
www.hepc8690.com info@hepc8690.com
www.hepc8690.ca/PDFs/initialClaims/tran5-e.pdf

Pre-86/Post-90

Administrator 1-866-334-3361
preposthepc@crawco.ca
www.pre86post90settlement.ca
Settlement Agreement: http://www.reko.ca/html/hepc_settleagreement.pdf

COMING UP IN BC/YUKON:

Armstrong HepCURE Contact: 1-888-437-2873 Phone support.

AIDS Vancouver Island HCV support
- **Campbell River**: Drop in, harm reduction, support, education. 1371 C - Cedar St. Contact: 250-830-0787 leanne.cunningham@avi.org
- **Comox Valley** 355 6th St. Courtenay; Contact Sarah 250-338-7400 sarah.sullivan@avi.orgDrop in, harm reduction, support, education.
- **Nanaimo** Info: Contact Anita 250-753-2437 anita.rosewall@avi.org
- **Port Hardy** (Port McNeil, Alert Bay, Port Hardy, Sayward, Sointula and Woss) 7070 Shorncliffe Rd, Contact Tom, 250-949-0432 tom.fenton@avi.org. Education, harm reduction, support, drop-in kitchen.
- **Victoria** 1601 Blanshard St., 250-384-2366 info@avi.org Harm Reduction.

Boundary HCV Support and Education. Support, education, presentations. Contact Ken 250-442-1280 ksthomson@direct.ca

Castlegar Contact Robin 250-365-6137 eor@shaw.ca

Courtenay HCV Peer Support and Education. Contact Del 250-703-0231 dggrimstad@shaw.ca

Burnaby HCV Support Contact Beverly at 604-435-3717 batlas@telus.net

Cowichan Valley Hepatitis C Support Contact Leah 250-748-3432 r-l-attig@shaw.ca

Cranbrook HeCSC-EK Phone support. Contact Leslie 250-426-6078, ldlong@shaw.ca

HepCBC info@hepcbc.ca, www.hepcbc.ca
- **Victoria:** Peer Support Last Tues. monthly 7-8:30 PM, Victoria Health Unit, 1947 Cook St. **NEXT MEETING: June 30th** Drop-in/Office/Library, 306-620 View St.. Contact 250-595-3892 Phone support 250-595-3891 9 AM-10 PM
- **Fraser Valley** Support/info 604-576-2022

Kamloops AIDS Society of Kamloops (ASK Wellness Centre) HIV/HEPC Peer Support Group each Thurs. 11-2 PM, 433 Tranquille Rd. 250-376-7558 Support/ Referral. info@askwellness.ca 1-800-661-7541 www.aidskamloops.bc.ca

Kelowna Hepkop: Last Sat. monthly, 1-3 PM, Sep-May, Rose Ave. Meeting Room, Kelowna General Hospital. Contact Elaine 250-768-3573, eriseley@shaw.ca, Lisa 1-866-637-5144. ljmortell@shaw.ca

Mid Island Hepatitis C Society 2nd Thurs. monthly, 7 PM, (Location to be arranged.) Contact midislandhepc@hotmail.com

Nanaimo Hepatitis C Treatment Peer Support Group Meetings 1st & 3rd Thurs. Monthly 4-5 PM, AVI Health Centre, #216-55 Victoria Rd, Nanaimo. Contact Fran 250-740-6942. hepctxpeersupport@hotmail.com

Nakusp Support Contact. Contact Vivian 250-265-0073 Claire@columbiacable.net

Nelson Hepatitis C Support Group 1st Thurs. **every 2nd month, afternoons**. ANKORS Offices, 101 Baker St. Drop-in library M-Th 9-4:30. Contact Alex or Karen 1-800-421-2437, 250-505-5506, information@ankors.bc.ca alex@ankors.bc.ca www.ankors.bc.ca/

New Westminster Support Contact Dianne Morrissettie, 604-525-3790 before 9 PM. dmorrissettie@excite.com

North Island Liver Service - Viral Hepatitis Information, support and treatment, serving Fanny Bay North to Pt Hardy, Vancouver Island. Toll free 1-877-215-7005

Pender Harbour Contact Myrtle Winchester 604-883-0010 myrwin@dccnet.com

Powell River Hep C Support Powell River Community Health, 3rd Floor–5000 Joyce Ave. Contact: Rosemary rosemary.moran@vch.ca 604-485-3310

Prince George Hep C Support Group 2nd Tues. monthly, 7-9 PM, Prince George Regional Hospital, Rm. 421. Contact 250-963-9756, Ilse 250-565-7387 ilse.kuepper@northernhealth.ca

Princeton Contact the Health Unit (Princeton General Hospital) 250-295-4442

Prince Rupert Hep C Support Contact: Dolly 250-627-7942 hepcprincerupert@citytel.net

Queen Charlotte Islands/Haida Gwaii & Northern BC support. Contact Wendy 250-557-2487, 1-888-557-2487, wendy@wendyswellness.ca www.wendyswellness.ca http://health.groups.yahoo.com/group/Network-BC/

Slocan Valley Support Group Contact Ken 250-355-2732, ken.forsythe@gmail.com

Smithers: Positive Living North West Contact the Prince George group, please.

Sunshine Coast-Sechelt Healthy Livers Support Group Information/ resources, contact Catriona, 604-886-5613 catriona.hardwick@vch.ca or Brent,604-740-9042 brent.fitzsimmons@vch.ca

VANDU The Vancouver Area Network of Drug Users. 380 E Hastings St. M-F 10-4 Contact 604-683-6061 vandu@vandu.org www.vandu.org

Vancouver Pre/post liver transplant support Contact Gordon Kerr sd.gk@shaw.ca

Vancouver Hepatitis C Support Group Contact 604-454-1347 or 778-898-7211, or call 604-522-1714 (Shelley), 604-454-1347 (Terry), if you would like to talk or meet for coffee.

YouthCO AIDS Society HepCATS 900 Helmcken St, 1st floor, Vancouver 604-688-1441 or 1-877-YOUTHCO www.youthco.org Support program manager: Renaud Boulet renaudb@youthco.org

Vernon HeCSC HEPLIFE 2nd & 4th Wed. monthly, 10 AM-1 PM, The People Place, 3402-27th Ave. Contact 250-542-3092, hecsc@hepc.vernon.bc.ca

Whitehorse, Yukon—Blood Ties Four Directions Contact 867-633-2437

OTHER PROVINCES:

ONTARIO:

Barrie Hepatitis Support Contact Jeanie for info/appointment jeanievilleneuve@hotmail.com

Sandi's Crusade Against Hepatitis C/Durham Hepatitis C Support Group Contact Sandi: smking@rogers.com www.creativeintensity.com/smking/ http://health.groups.yahoo.com/group/CANHepC/

Hamilton Hepatitis C Support Group 1st Thurs. monthly, 6-7 PM, Hamilton Urban Core Community Health Centre, 71 Rebecca St, Hamilton. Contact Maciej Kowalski, Health Promoter 905-522-3233 mkowalski@hucchc.com

Hepatitis C Network of Windsor & Essex County Last Thurs. monthly, 7 PM, Teen Health Centre-Street Health Program Office, 711 Pelissier St., Suite 4, Windsor, ON. Contact Andrea Monkman: 519-967-0490 or hepcnetwork@gmail.com. http://hepcnetwork.net

Kingston Hep C Info HIV/AIDS Regional Service. Contact 613-545-3698, hars@kingston.net, www.hars.ca

Kitchener Area Chapter 3rd Wed. monthly, 7:30 PM, Zehrs Community Room, Laurentian Power Centre, 750 Ottawa St. S., Kitchener. Contact: Bob 519-886-5706 bc.cats-sens@rogers.com or Mavis 519-743-1922 elroym222@rogers.com

Niagara Falls Hep C Support Group Contact Rhonda 905-295-4260, kehl@talkwireless.ca

Owen Sound Info and support. Contact Debby Minielly, 1-800-263-3456 Ext. 1257, 519-376-9420, Ext. 1257, dminielly@publichealthgreybruce.on.ca www.publichealthgreybruce.on.ca/

Peel Region (Brampton, Mississauga, Caledon) Contact 905-799-7700 healthlinepeel@peelregion.ca

St. Catharines Contact Joe 905-682-6194 jcolangelo3@cogeco.ca

Sudbury Circle C Support Group 1st Tues. monthly. Contact Ernie 705-522-5156, hepc.support@persona.ca or Monique 705-691-4507.

Toronto CLF First Mon. monthly Oct. through June, 7:30 PM, North York Civic Centre, 5100 Yonge Street. More info: www.liver.ca. Contact Billie 416-491-3353, bpotkonjak@liver.ca

Thunder Bay Hep C support. Contact Janet Adams 807-345-1516 (or for 807 area only 1-800-488-5840)

Unified Networkers of Drug Users Nationally undun@sympatico.ca

York Region Hepatitis C Education Group 3rd Wed. monthly, 7:30 PM, York Region Health Services, 4261 Hwy 7 East, B6-9, Unionville. Contact 905-940-1333, 1-800-361-5653 info@hepcyorkregion.org www.hepcyorkregion.org

QUEBEC:

Quebec City Region Contact Renée Daurio 418-836-2307 reneedaurio@hotmail.com

ATLANTIC PROVINCES:

Cape Breton Island, NS The Hepatitis Outreach Society Support Group 2nd Tues. monthly 150 Bentinck Street, Sydney, NS. 7-9 PM. Call 1-800-521-0572, 902-733-2486 info@hepatitisoutreachsociety.com.

PRAIRIE PROVINCES:

Edmonton Contact: Jackie Neufeld 780-939-3379.

Wood Buffalo HIV & AIDS Society #002-9908 Franklin Ave, Fort McMurray, AB Contact 780-743-9200 wbhas@telus.net ww.wbhas.ca

Manitoba Hepatitis C Support Community Inc. Each 2nd & last Tues. monthly, 7 PM, United Church, Crossways-in-Common, 222 Furby St., side door, Main Floor. Look for signs. Everyone is welcome. Contact Kirk: 204-772-8925 info@mbhepc.org www.mbhepc.org

Medicine Hat, AB Hep C Support Group 1st & 3rd Wed. monthly, 6:30 PM, HIV/AIDS Network of S.E. AB Association, 550 Allowance Ave. Contact 403-527-7099 bettyc2@hivnetwork.ca

TIP OF THE MONTH:

GET TESTED.
GET INFO.
DON'T PASS HEP C ON!

If you have a Canadian HCV support group to list here, please send details to info@hepcbc.ca by the 15th of the month. It's free!

REPORT ADVERSE EVENTS

Report problems with medical products, including product use errors, product quality problems, and serious adverse events. *www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm*