HCMSG

The Hepatitis C Mentor & Support Group

PATIENT SUPPORT NEWSLETTER

Vol. 1.2 Fall 2013

WELCOME from Ronni Marks, Founder & Director HCMSG

I was diagnosed with Hepatitis C in 1997, a time when the internet was new and there were no Hepatitis C support groups. My friends and family didn't understand what I was going thru. I made a promise that if possible, I would never let anyone else endure this experience alone!

My organization HCMSG-the Hepatitis C Mentor and Support Group, was formed to address the lack of awareness, support and services for people living with hepatitis C, co-infection, pre and post liver transplant.

My hope is that this newsletter will be a form of support to those newly diagnosed, just dealing, making decisions, on treatment and even after treatment. We welcome your suggestions on what you would like to see in upcoming issues and any stories you want to share. We can be reached at hepatitisCmsg@gmail.com.

BREAKING NEWS
Mary Olson, DNP, ANP – Research Nurse Manager

10/24/2013: Janssen Research & Development, LLC announced that the FDA advisory committee recommended approval of simeprevir given with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C infection.

Simeprevir (TMC435) is an investigational NS3/4A protease inhibitor dosed as a 150mg capsule once daily with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease for 24 or 48 weeks.

The Phase 3 data for this regimen have an overall sustained viral response 12 weeks after completing treatment (SVR12) of 80-81% for naïve patients.

10/25/2013: Gilead announced that the FDA advisory committee supports the approval of Sofosbuvir. The final FDA decision is anticipated by 12/8/2013. The FDA committee voted unanimously that the data support the use of sofosbuvir and ribavirin in genotype 2 and 3 HCV infection. The committee also voted unanimously that data supports the use of sofosbuvir in combination with pegylated interferon (Peg-INF) and ribavirin (RBV) for the treatment of naïve patients with genotype 1 and 4.

Data from the Sofosbuvir Phase 3 studies are listed below:

Study:	*Population:*	*Tx Groups:*	*SVR12 Rates*
NEUTRINO	Genotype 1/4/5/6 tx naïve	Sofosbuvir+RBV+Peg-IFN for 12 weeks	90%
FISSION	Genotype 2/3 tx naïve	Sofosbuvir+RBV for 12 weeks Peg-INF+RBV for 24 wks or	67% 67%
POSITRON	Genotype 2/3, IFN intolerant, ineligible or unwilling	Sofosbuvir + RBV for 12 wks Placebo for 12 wks	78% 0%
FUSION	Genotype 2/3 tx experienced	Sofosbuvir +RBV for 12 wks or Sofosbuvir +RBV for 16 wks	50% 73%

4/5/2013: Fibroscan was approved by the FDA for use in the United States. Examination with Fibroscan, also called transient elastography, is a technique used to assess liver stiffness (measured in kPA correlated to fibrosis) without invasive investigation. The result is immediate; it shows the condition of the liver; and allows health care providers to diagnose and monitor disease evolution in conjunction with treatment and collateral factors.

NEWS WATCH FOR 2015

Direct acting antiviral (DAA) combination without interferon.

Daclastasvir, asunaprevir and BMS-791325 was studied in treatment naïve patients with genotype 1 HCV with and without cirrhosis. Patients were treated for 24 or 12 weeks, and the SVR24 rates were 88-94% respectively.

The *AVIATOR* trial compared combinations of DAAs with or without ribavirin for varying treatment duration in patients with HCV genotype 1 infection. The regimen containing 3 DAAs (ABT-450, ABT-267, ABT-333) with ribavirin for 12 weeks reported SVR12 rates of 98% in treatment naïve and 93% in prior null responders.

The *LONESTAR* study using sofosbuvir with ledipasvir with and without ribavirin noted SVR8 response rates after 8 weeks of treatment in naïve HCV genotype 1 patients of 95-100%. SVR4 rate after 12 weeks of treatment was 100% in the treatment naïve group and 95% in the treatment experienced groups.

TREATMENT SIDE EFFECT MANAGEMENT TIP

Pegylated interferon based regimens and regimens that include ribavirin can cause nausea. Ginger can be taken to decrease the nausea. Ginger can be eaten raw or in foods that contain ginger such as ginger tea, ginger ale or ginger candy.

REFERENCES

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HEPATITIS TERMINOLOGY

HEPATITIS: inflammation of the liver. Hepatitis may have various causes, including viruses, toxins, and heavy alcohol consumption.

STANDARD OF CARE: the level of care that all persons with a particular illness should receive; the level below which care would be considered substandard.

STANDARD THERAPY: the best or most widely used currently available treatment for a disease.

GENOTYPE: the genetic makeup of an organism. HCV has six major genotypes (designated by the numbers 1 through 6). In the U.S., genotype 1a/b is most prevalent, and also more difficult to treat.

SUBTYPE: a genetic variation of an organism. Subtypes are a more narrow classification than genotypes, but broader than quasispecies. Genotype 1 HCV is divided into subtypes 1a and 1b.

CIRRHOSIS: a type of liver damage in which normal liver cells are replaced with fibrous scar tissue. In compensated cirrhosis, the liver is damaged but can still function. In decompensated cirrhosis, liver function is severely impaired and scar tissue interferes with normal blood flow through the liver, potentially leading to bleeding varices, ascites, "brain fog," and other symptoms.

CLEARANCE: removal or elimination, e.g., of a virus or drug from the body

FIBROSIS (adjective FIBROTIC): liver damage in which fibrous tissue develops and replaces normal cells.

Stage of Hepatitis: how advanced is the hepatitis. Usually there are several stages. With Hepatitis, these are the acknowledged stages:

> *STAGE I:* the earliest stage of liver damage, characterized by liver inflammation without fibrosis or cirrhosis.
>
> *STAGE II:* a stage of liver damage characterized by fibrosis in a single area of the liver.
>
> *STAGE III:* a stage of liver damage characterized by fibrosis in adjacent areas of the liver.
>
> *STAGE IV:* the most advanced stage of liver damage, characterized by cirrhosis and loss of normal liver architecture.

HALF-LIFE: the time required for half of the original amount of a drug to be eliminated from the body, or for a drug to decrease to half its original concentration in the blood.

HCV RNA: the genetic material of the hepatitis C virus. A detectable level of HCV RNA on a viral load test indicates that HCV is actively replicating.

SUSTAINED VIROLOGICAL RESPONSE (SVR): HCV RNA is undetectable at Week 24 post-treatment. Also called a viral cure.

SUSTAINED RESPONDER: a person who maintains a long-term response to treatment. In HCV, a sustained responder has a long-term response (e.g., normal ALT levels, undetectable HCV RNA) that persists after treatment is stopped.

Many of these explanations taken from:
http://www.hcvadvocate.org/library/glossary.asp#s

Questions to Ask Your Health Care Provider

You have been diagnosed with hepatitis C (whether it was yesterday or 10 years ago), and you are in the process of scheduling a follow up appointment with your Primary Care Provider. The disease, treatments, and the next steps can be overwhelming. To help you through this process, below we have listed out some of the questions you might want to pose to your provider. Remember a few things though: write your questions down before the visit; take notes during the visit; you might even want someone to go with you; and not everything can and will be addressed in the one visit. Your partnership with your primary care provider should be a collaborative and ongoing dialogue. But remember at the end of the day – this is about YOU – you are the boss – the providers are the consultants and here to guide you along the journey.

Possible questions when first diagnosed with Hepatitis C:

- What are the symptoms of hepatitis C?
- What are the long-term effects of hepatitis C?
- Should I be immunized for hepatitis A or hepatitis B?
- How can I prevent further damage to my liver?
- How do alcohol and other drugs affect my liver?
- For women, does my diagnosis affect the ability to have children?
- Are my family members at risk of contracting hepatitis C?
- Can I give it to my loved ones/friends?
- Should my family members be tested?
- Will I need to see a specialist to be treated?

Pre-Treatment and During Treatment Questions:

- What types of treatment are available?
- What are the success rates of each type of treatment?
- What are the side effects of treatment?
- Are there any long-term side effects?
- What are the advantages and disadvantages of treatment?
- How long will my treatment last?
- Will I be cured after treatment?
- What are the alternatives to treatment?
- How safe are alternative therapies?
- What is my genotype?
- How will my genotype respond to treatment?
- What is a biopsy?
- Will I need a biopsy?
- How are biopsy results interpreted?
- What kinds of tests will I need to begin treatment?
- Will I need a psychological evaluation before starting treatment?
- Will I need any other special evaluation before starting treatment?
- What do I need to do to physically and/or mentally prepare for treatment?
- Will my insurance cover treatment?
- If I do not have insurance, am I eligible for clinical trials or patient assistance programs? (See patient assistance programs section)

During Treatment Questions

- How can I minimize the side effects of treatment?
- Under what circumstances would treatment be stopped earlier than planned?
- Do I have to take my medication at the same time every day?
- What happens if I miss a dose?
- How does alcohol affect treatment or viral response?
- What if I get very weak and anemic?
- What if I get very depressed during the treatment?

Post-Treatment:

- What is sustained viral response?
- How long will I continue to need lab tests after finishing treatment?
- How long will side effects last after treatment ends?
- When can I expect to feel better?
- Will I have any lifestyle or diet restrictions?
- Do I still have to protect my liver?
- Can I resume alcohol consumption?
- What does non-response mean?

- What happens if I am a non-responder? What are my other options?

Six (6) Must-Ask Questions about Medications

What do good mystery novels and new prescriptions have in common? Both can keep you guessing.

Doctors should communicate six basic points whenever they prescribe a new medication. Unfortunately, research shows they usually deliver only about four of them. For the full story, ask these six critical questions when you are given a new drug:

1. What's the name (trade or generic) of the medication?
2. Why are you prescribing it for me?
3. What are the potential side effects?
4. How much should I have (how many pills, squirts, teaspoons, etc.)?
5. How many dose(s) do I need each day, and what time should I take them?
6. For how long should I take the medication?

Not taking your medication correctly can make you look as much as 4.5 years older. It can also lead to some serious health trouble, such as a hospital stay for side effects, an unintentional overdose, or a relapse of your original condition. Nevertheless, about 50 percent of people who need medications for the long term to manage health conditions stop taking them within 6 months of their last doctor's appointment -- a major no-no.

Whether you quit your pills because you did not know the answer to question 6, or because you feel better, experience side effects, or want to save money, there's really only one good reason you should ever stop taking your medication: Your doctor tells you to.

So help your doctor help you. Jot down notes about your medications, ask for printed information -- do whatever it takes to make instructions crystal clear. Then, follow doctor's orders. www.realage.com/news_features/tip.aspx?cid=17682&#MI

CLINICAL TRIALS

New HCV treatment options in development may be available through participation in clinical trials. Clinical trials require that you meet the inclusion and exclusion criteria. To inquire about participation contact one of the centers below. These centers generally complete an intake interview and perhaps collect records. If you are a candidate for clinical trials, you will be offered a trial if one is available or contacted at a future date when a trial is available. TAG (Treatment Action Group) provides an excellent overview to clinical trials entitled: Guide to Clinical Trials for People with Hepatitis C - Second Edition by Matt Sharp and Tracy Swan. Please access it at the following address: http://www.treatmentactiongroup.org/hcv/publications/2011/hcv-clinical-trials-guide

Center Watch Clinical Trials Listing Service

The site is designed to be an open resource for patients interested in participating in clinical trials and for research professionals. www.centerwatch.com/patient/ifcn_00.html

Veritas Medicine
A free, confidential resource providing access to clinical trials and information on treatment options. www.veritasmedicine.com

ClinicalTrials.gov (a service of the National Institutes of Health-NIH) Provides regularly updated information about federally and privately supported clinical research in human volunteers. The Website gives information about a trial's purpose, who may participate, locations, and phone numbers. For more details, visit: www.clinicaltrials.gov

Emory Mind-Body Program
The Emory University Mind-Body Program is committed to understanding the side effects associated with interferon-alpha treatment for hepatitis C. This website gives information about current clinical trials at Emory University. www.psychiatry.emory.edu/PROGRAMS/mindbody

Volunteering for a Clinical Trial, a brief educational pamphlet. If you would like to order this pamphlet, click here: www.centerwatch.com/bookstore/pubs_cons_brochureform.html

CURRENT CLINICAL TRIALS & CENTERS in the NYC Region:

NYU LANGONE MEDICAL CENTER
Dr. Samuel Sigal
Therese Capobianco 212-263-3643

CONCORDE MEDICAL GROUP
Drs. Hillel Tobias/Edward Brettholz
Juanita Clinical Trial Coordinator 212-889-5544

WEILL CORNELL MEDICAL COLLEGE
Dr. Ira Jacobson
Mary Olson, DNP, ANP 646-962-4372

MT SINAI MEDICAL CENTER
Dr. Douglas Dietrich
Maura Laverty 212-241-7734

COLUMBIA UNIVERSITY MEDICAL CENTER

Dr. Robert Brown
Theresa Lukose, Pharm.D. 212-305-3839

NORTHSHORE MEDICAL CENTER

Dr. David Bernstein
Radica Palmer, RN 516-562-2082

MONTICELLO, NY
Dr. Gary Good
Kathleen or Teresa 845-794-6813

PATIENT ASSISTANCE PROGRAMS

Do you lack health insurance but make too much money to qualify for government assistance? Are your prescription co-payments so high that you can't afford other basic necessities? Help may be available from pharmaceutical companies in the form of patient assistance programs (PAPs) and co-pay programs.

Over the past two years, the Fair Pricing Coalition (FPC) has been working closely with the pharmaceutical industry to streamline access to co-pay programs and PAPs for people living with viral hepatitis. The FPC has negotiated co-pay programs with virtually every major hepatitis drug manufacturer. Following is a list of co-pay and patient assistance programs for hepatitis C and contact information for these programs. This is a living document that will be updated as program changes are implemented.

Fro more information about patient assistance programs and fair pricing, please check out the following two excellent resources: www.fairpricingcoalition.org and. http://www.hepatitisCmsg.org/assistance-programs.html.

Source: http://www.hepmag.com/articles/hepatitis_paps_copays_20506.shtml

The following websites also provide additional information on patient assistance programs:
http://www.scbn.org/?gclid=CJDt5NHAkboCFQ-g4AodLVQAIQ
http://www.hcvadvocate.org/hepatitis/factsheets_pdf/Patient%20Assistance%20Programs.pdf
http://www.hepatitisfoundation.org/pdfs/Resource/0612-CoPayHelp.pdf

If you wish us to email you the newsletter and/or just want to contact us with news, questions, thoughts, etc., please contact us at hepatitisCmsg@gmail.com. Check out our website www.hepatitisCmsg.org for more information, support, and assistance.

Thank you!

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