FDA Approves New Hep C Combo, Gilead's Harvoni (Ledipasvir/Sovaldi)

October 21, 2014 By Connie M. Welch

October 10th, the FDA approved new hep C combo Harvoni, the first once-daily single tablet regimen for hepatitis C genotype 1. Harvoni by Gilead Sciences may be dubbed "the one hit wonder" which combines the brand new drug ledipasvir, an NS5A inhibitor with the nucleotide analog polymerase inhibitor sofosbuvir (Sovaldi) which was approved December 2013.

This new treatment combo is a game changer for hepatitis C patients on many levels. Harvoni achieved cure rates (SVR12) of 94 to 99% in three phase 3 studies.Treatment duration is shortened to just 8 weeks for certain treatment-naÃ¯ve patients without cirrhosis and a baseline viral load below 6 million. Harvoni eliminates the need for iterferon and ribavirin for patients with genotype 1.

Standard treatment duration with Harvoni is 12 or 24 weeks depending on prior treatment history, cirrhosis status and baseline viral load.

Nezam Afdhal M.D. Director of Hepatology at Beth Israel Deaconess Medical Center, Professor of Medicine at Harvard Medical School states, "*By providing very high cure rates in as little as eight weeks and completely eliminating the need for interferon and ribavirin, which are challenging to take and tolerate, Harvoni significantly advances treatment for patients with the most common form of hepatitis C in the United States. And for the first time, the vast majority of patients can be cured with a once-daily pill in only 8 to 12 weeks.*"

SVR12 Cured

Gilead reports patients who achieve SVR12 are cured of Hepatitis C. An SVR12 stands for sustained virological response after 12 weeks of treatment which means, after patients complete the course of treatment a blood test for viral load test is taken again after 12 weeks of post treatment to see if the hep C virus is still present, if it remains non-detected, the patient is cured.

Genotypes

There are at least 6 known genotypes for hepatitis C (genotypes 1-6) and more than 50 subtypes have been identified. Genotype 1 is the most common HCV genotype in the United States and the hardest type to fight.

Great Progress from 10 Months Ago; Then and Now

December 2013 until now, the treatment offered with Sovaldi for genotype 1 is used in combination with ribavirin and interferon, 12 weeks of treatment and a 90% cure rate. For those who cannot tolerate the side effects of Interferon and ribavirin and off-label combo of Sovaldi and Olysio, by Janssen (Johnson & Johnson) has been prescribed by physicians.

December 2013 Gilead Sciences opened the door to the first hep C treatment offered without Interferon to patients with genotype 2 with Sovaldi and rbavirin, 12 weeks of treatment and a 90% cure rate.

Today, we are waving goodbye to interferon and severe side effects of the past and ushering in a new generation of effective treatments for hep C.

Side Effects of Harvoni and Important Safety Information
Most common side effect reported (>10%. all grades) adverse reactions were fatigue and headache for those treated for 8, 12 or 24 weeks.

Other side effects listed by the FDA reports less than 10% of patients reported additional side effects of nausea, diarrhea and insomnia.

Laboratory abnormalities of elevations of bilirubin and lipase in a small percentage of patients were observed.

Risk of Reduced Therapeutic Effect of Harvoni Due to P-gp Inducers: rifampin and St. John's wort are not recommended for use with Harvoni as they may significantly decrease ledipasvir and sofosbuvir plasma concentrations.

In addition to rfampin and St. John's wrt, there are other drug interactions that need to be considered before taking Harvoni, see list of these drugs at Harvoni/Gilead.

Gilead Offers U.S. Patient Support Program
To assist eligible HCV patients in the United States with access to Harvoni, Gilead has added the medicine to its Support Path program at www.MySupportPath.com.

The program offers a variety of support services for patients and providers which include:

- Call centered staffed with trained associates to help patients and their providers with insurance-related needs.
- 24-7 Nursing Support Service line.
- The Harvoni and Sovaldi Co-pay Coupon Programs which provide co-pay assistance for eligible patients with private insurance who need assistance paying for out-of-pocket medication costs. Most patients will pay no more than $5 per co-pay.
- The Support Path Patient Assistance Program, which will provide Harvoni and Sovaldi at no charge for eligible patients with no other insurance options.
- Gilead also provides support to independent non-profit organizations that provide assistance for eligible federally-insured and private-insured patients who need help covering out of pocket medication costs.

References:
To learn more about Harvoni or Sovaldi see, MySupportPath.com or call 1-855-769-7284 between 9:00am to 8:00pm Eastern time, Monday through Friday.
Center for Disease Control and Prevention

Are you waiting for the new hep C treatment without interferon or ribavirin? Questions or Comments, we'd love to hear from you.

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