FDA Approves Epclusa by Gilead, New Hep C Treatment for All Genotypes

July 6, 2016 By Connie M. Welch

June 28, 2016 The US FDA approved the first pan-genotypic (for all genotypes) combination tablet of Epclusa (sofosbuvir/velpatasvir), which is a once-daily fixed dose treatment for Hepatitis C. Epclusa is made by Gilead Sciences who is the current pharma leader with Hepatitis C treatment Harvoni (ledipasvir/sofosbuvir) and Sovaldi (sofosbuvir).

Epclusa will bring great benefits to suffering Hep C patients worldwide with new Hep C treatment now able to treat all genotypes (1-6) for patients with and without cirrhosis (advanced liver disease).

The FDA reports Epclusa is approved for Hepatitis C treatment in combination with and without ribavirin. Epclusa also provides another treatment option for Hep C patients with genotype 2 and 3 who may be able to use Epclusa without ribavirin which can cause anemia and other side effects.

Cure Rate

An average 98% SVR (sustained virologic response) cure from Hep C was shown in clinical trial studies with Hep C patients who did not have cirrhosis or those who had compensated cirrhosis.

An 83% to 94% SVR, cure rate was reported for patients in clinical trials who had decompensated cirrhosis (Child-Pugh B).

Treatment Time

Standard treatment time for majority of Hep C patients was 12 weeks.

Dosage

The recommended dosage of Epclusa is a once daily combination tablet of (sofosbuvir/velpatasvir), to be used with or without ribavirin.

Common Treatment Side Effects

The most common treatment side effects of Epclusa include headache and fatigue. If ribavirin is used, side effects of ribavirin can include possible anemia, fatigue, nausea, headache, insomnia and diarrhea were reported in clinical trials.

Warning and Precautions

FDA reports Epclusa carries a warning for patients and health care providers that serious slowing of the heart rate (symptomatic bradycardia) and cases requiring pacemaker intervention have been reported when amiodarone (heart medication) is used with sofobuvir in combination with another HCV direct-acting antiviral. Co-administration of amiodarone with Epclusa is not recommended. Epclusa also carries a warning not to use with certain drugs that may reduce the amount of Epclusa in the blood which could lead to reduced efficacy of treatment.

Coadminstration of Epclusa is not recommended with topotecan or proton-pump inhibitors, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, efavirenz, and tipranavir/ritonavir.

See full label instructions at drugs@fda and at www.gilead.com

Cost of Treatment

Gilead set the price of Epclusa at $74,760 for a standard 12 week treatment regimen. This price comes in below AbbVie's Technivie (ombitasvir/paritaprevir/ritonavir) which sells for $76,653. The highest Hep C treatment to date is Harvoni which costs $94,500. Gilead has the lowest cost of Hep C treatment with Harvoni, for Hep C patients whose liver condition qualifies for the 8 week treatment regimen at the cost of $63,000.

*Correction on lowest cost of treatment to this date June 2016, Merck's Hep C treatment Zepatier for genotypes 1 and 4 is the lowest cost treatment to date with a $54,600 price tag for a 12 week standard treatment time. This treatment can be used with or without Harvoni. If Ribavirin is needed, this medication is an additional cost.

U.S. Patient Support Program

Gilead has added Epculsa to its Support Path (www.MySupportPath.com) The program consists of an integrated offering of support services for patients and providers, including many assistance options for patients. Some of the assistance includes:

- Call center with trained associates to help patients and their providers with insurance related needs.
- 24-7 Nursing support service line
- Epculsa Co-pay Coupon program which provides co-pay assistance for eligible patients with private insurance who need assistance paying out of pocket costs. Most patients will pay no more than $5 co pay.
- Support Path Patient Assistance Program, will provide Epculsa at no charge for eligible patients with no other insurance options.

- Learn more about this program at Support Path for Epculsa, MySupportPath.com or call 1-855-769-7284 between 9:00am-8:00pm Eastern time, Monday through Friday.

Game Changer for Hep C

Gilead states, “As the first and only pan-genotypic cure for hepatitis C, Epclusa has the potential to eliminate the need for genotype testing, which can be a barrier to treatment in certain resource-constrained settings. We look forward to making Epclusa available to patients around the world as quickly as possible.”

Ira Jacobson, M.D, Chairman of the Department of Medicine at Mount Sinai Beth Israel, New York City and a principal investigator in Epculsa clinical trials states, “The approval of Epculsa represents an important step forward in the global effort to control and potentially eliminate HCV as it provides a safe, simple and effective cure for the majority of HCV-infected patients, regardless of genotype.”

Gilead states, “It is committed to helping enable access to Epclusa around the world. Gilead works with a network of regional business partners, generic licensing partners, the Medicines Patent Pool and other stakeholders to expand treatment globally. Epclusa is already licensed to Gilead’s 11 Indian manufacturing partners who may now begin production and distribution of a generic version of this medicine for 101 developing countries.

For more information see Gilead’s full Epclusa information press release.

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