FDA Approves Gilead's Vosevi for Re-treatment of Hepatitis C

The triple-drug regimen comes in a once-daily single tablet.

July 18, 2017

The Food and Drug Administration (FDA) has approved 12 weeks of Gilead Sciences' Vosevi (sofosbuvir/velpatasvir/voxilaprevir) for the re-treatment of adults with all genotypes of hepatitis C virus (HCV) who do not have cirrhosis or who have compensated cirrhosis (the milder form of the severe liver disease).

More specifically, the approval is for a second hep C treatment for those with genotypes 1, 2, 3, 4, 5 or 6 who were previously treated with an HCV regimen containing a direct-acting antiviral (DAA) from the NS5A inhibitor class or for those with genotype 1a or 3 who were previously treated with a Sovaldi (sofosbuvir)-containing regimen that did not include an NS5A inhibitor.

Vosevi is a once-daily fixed-tablet regimen that includes the polymerase inhibitor sofosbuvir, the NS5A inhibitor velpatasvir and the NS3/4A protease inhibitor voxilaprevir. It is the first hep C treatment approved for those who have been previously treated with Sovaldi (sofosbuvir)-containing regimens or with drugs from the NS5A inhibitor class.

Sovaldi is also included in Gilead's Harvoni (ledipasvir/sofosbuvir) and Epclusa (sofosbuvir/velpatasvir) and may be paired with drugs manufactured by other pharmaceutical companies, including Bristol Myers-Squibb's Daklinza (daclatasvir) or Janssen's Olysio (simeprevir).

Approved NS5A inhibitors include Daklinza, the velpatasvir component of Epclusa, the ledipasvir component of Harvoni, the ombitasvir component of Technivie (ombitasvir/paritaprevir/ritonavir) and the Viekira regimen (ombitasvir/paritaprevir/ritonavir; dasabuvir), and the elbasvir component of Zepatier (grazoprevir/elbasvir).

The FDA's approval was based on data from the Phase III POLARIS-1 study, which evaluated 12 weeks of Vosevi treatment among adults with genotypes 1 through 6 of HCV, including those without cirrhosis or who had compensated cirrhosis who had not been cured through previous treatment with a DAA regimen containing an NS5A inhibitor.

The approval was also based on data from the Phase III POLARIS-4 study, which evaluated 12 weeks of Vosevi among adults with genotypes 1a and 3 who did not have cirrhosis or who had

compensated cirrhosis and who had not been cured by previous treatment with a Sovaldi-containing regimen that did not include an NS5A inhibitor.

In the pooled results of these populations from POLARIS-1 and -4, 340 of 353 people (96 percent) who received Vosevi achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

The most common adverse health events reported by 10 percent or more of participants who received Vosevi in these trials were headache, fatigue, diarrhea and nausea. Only 0.2 percent of participants who received 12 weeks of Vosevi permanently stopped treatment because of adverse health events.

The FDA has given Vosevi a boxed warning in its product label concerning the risk of hepatitis B virus (HBV) reactivation among those coinfected with HBV and HCV. This warning applies to all DAA treatments for hep C.

There is also the potential for a serious reaction between Vosevi—as well as Sovaldi, Harvoni and Epclusa—and the heart drug Cordarone (amiodarone) that can lead to a serious, potentially fatal condition known as bradycardia, or slow heart rate.

To read a press release about the approval, click here.

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