FDA OKs Gilead’s Vosevi as Round Two Treatment

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The Food and Drug Administration (FDA) has approved 12 weeks of Gilead Sciences’ once-daily, single-tablet regimen 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 Vosevi approval is for a second hep C treatment for those with genotypes 1, 2, 3, 4, 5 or 6 who were previously treated with a hep C regimen containing a direct-acting antiviral from the NS5A inhibitor class or for those with genotype 1a or 3 who were previously treated with a sofosbuvir-containing regimen that did not include an NS5A inhibitor.

As an individual drug, Gilead’s sofosbuvir is sold under the brand name Sovaldi. It is also included in the pharmaceutical company’s Harvoni (ledipasvir/sofosbuvir) and Epclusa (sofosbuvir/velpatasvir) and may be paired with drugs manufactured by other 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 AbbVie’s Technivie (ombitasvir/paritaprevir/ritonavir) and of the Viekira regimen (ombitasvir/paritaprevir/ritonavir; dasabuvir) and the elbasvir component of Merck’s Zepatier (grazoprevir/elbasvir).

The FDA’s approval was based on data from two Phase III studies that included 353 participants matching the demographics of those for whom Vosevi was approved. The treatment boasted a 96 percent cure rate among them.

The most common adverse health events reported in these trials were headache, fatigue, diarrhea and nausea.

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