Gilead Seeks FDA Approval for Hep C Treatment for All Genotypes

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Gilead Sciences has filed a new drug application with the U.S. Food and Drug Administration (FDA) for approval of the once-daily, fixed-dose combination tablet of Sovaldi (sofosbuvir) and the investigational drug velpatasvir to treat those with genotypes 1 through 6 of hepatitis C virus (HCV). The application is backed up by clinical trials that tested 12 weeks of Sovaldi/velpatasvir among participants with the same range of genotypes, including those with compensated cirrhosis, as well as 12 weeks of the tablet plus ribavirin among participants with decompensated cirrhosis, the more advanced form of the liver disease.

Sovaldi, approved in December 2013, is a nucleotide analog polymerase inhibitor and is included in Gilead's blockbuster hep C combination tablet treatment Harvoni (ledipasvir/sofosbuvir), which is approved to treat genotype 1 of the virus. Velpatasvir is a pan-genotypic (meaning it affects all genotypes of hep C) NS5A inhibitor. Ledipasvir, the other drug in Harvoni, is also an NS5A inhibitor, but not pan-genotypic.

"As the first fixed-dose combination of two pan-genotypic, direct-acting antivirals, [Sovaldi/velpatasvir, or SOV/VEL] represents an important step forward in the treatment of patients with hepatitis C," Norbert Bischofberger, PhD, executive vice president of research and development and chief scientific officer at Gilead, said in a press release. "Genotype 1 is the most prevalent form of HCV in the United States; but worldwide, more than half of people living with HCV are infected with other genotypes. SOF/VEL complements our current HCV portfolio of Sovaldi and Harvoni, offering high cure rates and the potential to simplify treatment and eliminate the need for HCV genotype testing."

The FDA has already given Sovaldi/velpatasvir a breakthrough therapy designation, which is given to investigational therapies that may offer major advances over existing treatments.

Gilead's application for FDA approval of the treatment is supported by the four Phase III ASTRAL trials, which boasted excellent cure rates. For the most part, between 94 and 100 percent of participant groups were cured, which is comparable to the success rates seen in clinical trials of Harvoni as well as AbbVie's Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir) and Technivie (ombitasvir/paritaprevir/ritonavir). The ASTRAL-4 trial results suggest that such a high success rate for those with decompensated cirrhosis will likely require their taking ribavirin in addition to Sovaldi/velpatasvir.

The strong results of the ASTRAL trial, coupled with the fact that Sovaldi/velpatasvir can be used among all genotypes, puts Gilead in a position to continue dominating the hep C market in 2016.

To read a Gilead press release on the FDA application, click here.
