Gilead Files for FDA OK of New All-Genotype Hepatitis C Treatment

The triple-drug combo would be the first once-daily, single-tablet regimen for those with all genotypes who've failed a previous treatment.

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Gilead Sciences has filed a new drug application with the U.S. Food and Drug Administration (FDA) for approval of its fixed-dose, single-tablet combination regimen of sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX) to treat all genotypes of hepatitis C virus (HCV). If approved, the triple-drug combination tablet would be the first pangenotypic (meaning it works on all viral genotypes) once-daily, single-tablet regimen approved for those who have failed a previous direct-acting antiviral (DAA) hep C treatment.

The new drug application is based on data from the Phase III POLARIS-1 and POLARIS-4 trials. Each of these studies tested 12 weeks of SOF/VEL/VOX among 430 people with genotypes 1 through 6 of hep C who were previously treated with DAAs, including an NS5A inhibitor. Ninety-seven percent of the participants achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

Two other Phase III studies, POLARIS-2 and -3, also supported Gilead's application. These studies, which included people with cirrhosis, tested eight weeks of the triple-drug combination treatment among 611 people who had not been treated for HCV before. Ninety-five to 96 percent of the participants were cured.

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

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

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