FDA OKs Harvoni for Hep C Genotypes 4, 5, 6, People With HIV

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The U.S. Food and Drug Administration (FDA) has approved new indications for Gilead Sciences' Harvoni (ledipasvir/sofosbuvir): to treat hepatitis C virus (HCV) in those with genotypes 4, 5 and 6 of the virus and in those who are coinfected with HIV. Additionally, the FDA approved Harvoni plus ribavirin as an alternative to 24 weeks of Harvoni for treatment-experienced people with genotype 1 and cirrhosis.

Harvoni was approved in October 2014 to treat genotype 1 of the virus.

Gilead's application to the FDA for the genotype 4 through 6 designations was based on data from the 1119 and ELECTRON-2 trials. In the 1119 trial, 12 weeks of Harvoni cured 93 percent (38 of 41) of those with genotype 4 and 93 percent (38 of 41) of those with genotype 5. In ELECTRON-2, 12 weeks of treatment cured 96 percent (24 of 25) of treatment-naive and treatment-experienced people with genotype 6.

The application for the HIV coinfection indication was supported by data from the Phase III ION-4 trial, which examined 12 weeks of Harvoni among HIV/HCV-coinfected people with genotype 1 or 4. Ninety-six percent (321 of 335) were cured. Forty-five percent of the participants were treatment naive. Twenty percent had cirrhosis. The majority of the participants were taking one of three HIV antiretroviral regimens: Atripla (efavirenz/tenofovir/emtricitabine); Truvada (tenofovir/emtricitabine) and Isentress (raltegravir); or Complera (rilpivirine/tenofovir/emtricitabine).

The approval of 12 weeks of Harvoni plus ribavirin among cirrhotic people with genotype 1 was based on data from the Phase II SIRIUS study, which evaluated that regimen and treatment length, comparing it with Harvoni without ribavirin for 24 weeks among people with genotype 1 and compensated cirrhosis who had previously failed hep C treatment. Ninety-six percent (74 of 77) of those treated with Harvoni plus ribavirin for 12 weeks were cured, as were 97 percent (75 of 77) of those treated with 24 weeks of Harvoni alone.

To read a press release on the new FDA indications, click here.

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