Gilead Sciences' Harvoni Is Approved in Europe

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The European Commission has approved Gilead Sciences' hepatitis C virus (HCV) treatment Harvoni (ledipasvir/sofosbuvir), FirstWord Pharma reports. While in the United States the fixed-dosed combination tablet is only approved to treat those with genotype 1 of the virus, in Europe the approval includes those with genotypes 3 and 4 and people who are coinfected with HIV.

Harvoni is a daily pill that includes Gilead's NS5A inhibitor ledipasvir plus the company's nucleotide analog polymerase inhibitor sofosbuvir. In January 2014, the European Commission approved sofosbuvir as a stand-alone pill under the brand name Sovaldi.

The commission recommends Harvoni to treat treatment-naive and treatment-experienced people with genotype 1 or 4 of hep C with a treatment duration of 12 or 24 weeks, depending on treatment history and whether or not they have cirrhosis. Clinicians may consider just eight weeks of treatment for people with genotype 1 who are treatment naive and do not have cirrhosis. Twenty-four weeks of Harvoni plus ribavirin is recommended for people with genotype 1 or 4 who have decompensated cirrhosis, as well as for people with genotype 3 who have cirrhosis or who failed a previous cure attempt. All of these recommendations also apply for those who are coinfected with HIV.

"Genotype 1 patients living with hepatitis C in Europe and the physicians who treat them have been waiting for a treatment advance like this for decades," Graham Foster, MD, a professor of hepatology at Queen Mary University of London, said in a press release. "With Harvoni, we have the potential to transform the way we treat people living with the most prevalent form of hepatitis C in Europe. We can now expect very high [cure] rates, and for many patients, we can eliminate the need for interferon injections and ribavirin and offer a cure in a once-daily tablet."

To read a feature on Harvoni's U.S. approval, click here.

To read the FirstWord Pharma story, click here.

To read the Gilead press release, click here.