Europe Approves AbbVie’s New Hepatitis C Treatment

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The European Commission has followed the U.S. Food and Drug Administration (FDA) in approving AbbVie's hepatitis C virus (HCV) treatment, called Viekirax (ombitasvir/paritaprevir/ritonavir) and Exviera (dasabuvir) in Europe, The Wall Street reports. In the United States, the two-tablet regimen is marketed under a single name, Viekira Pak.

Viekirax and Exviera, to be taken with or without ribavirin, are now approved in Europe to treat people with genotype 1 of hep C, including those with compensated cirrhosis, HIV coinfection, those who are taking opioid substitution therapy and liver transplantees. Viekirax alone is also approved for people with genotype 4.

In contrast, the FDA did not approve Viekira Pak, the equivalent of Europe's Viekirax, to treat genotype 4. Nor did Viekira Pak receive an FDA indication for those on opioid substitution therapy.

For genotype 1, the regimen requires taking two tablets of Viekirax once a day, plus Exviera, with or without ribavirin, twice daily. Twelve weeks of treatment are recommended, except among people with genotype 1a who have cirrhosis, who should stay on the medications for 24 weeks.

Europeans with genotype 4 are advised to take Viekirax and ribavirin once a day for 12 weeks if they do not have cirrhosis and 24 weeks if they do.

"Hepatitis C is a complex disease, with multiple genotypes and special patient populations that need to be considered when determining the right treatment for an individual patient," Stefan Zeuzem, MD, a professor of medicine and chief of the department of medicine I at J.W. Goethe University Hospital in Frankfurt, Germany, said in a press release. "In clinical trials, AbbVie's treatment achieved high cure rates with low rates of discontinuation across a variety of patient populations, making it an important addition to the class of therapies that is changing the way hepatitis C is being treated."

To read the press release, click here.

To read the Wall Street Journal story, click here.

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