FDA Gives Priority Status to AbbVie’s Hep C Therapy for Genotype 4

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The U.S. Food and Drug Administration (FDA) has granted priority review status to AbbVie’s ombitasvir/paritaprevir/ritonavir plus ribavirin to treat genotype 4 of hepatitis C virus (HCV). The company announced the FDA’s decision, which cuts the review time for the new drug application from the typical 10 months to six months, at the 50th International Liver Congress in Vienna, Austria.

The FDA grants priority review to investigational therapies that, if approved, would provide a significant improvement in safety or effectiveness over available treatments. This would be the first all-oral treatment approved for genotype 4 of the virus.

The federal agency made its decision in part based on data from the open-label, Phase IIb PEARL-1 trial of the AbbVie regimen, in which 100 percent of genotype 4 participants without cirrhosis (42 of 42) or who had failed a previous interferon-based treatment (49 of 49) achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). In addition, 91 percent of treatment-naive participants (40 of 44) were cured after taking the regimen without ribavirin.

To read the AbbVie press release, click here.

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http://beta.docker.hepmag.com/article/AbbVie-priority-review-27112-266866719