AbbVie Seeks OK for Ribavirin-Free Viekira Pak for Hep C 1b

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The U.S. Food and Drug Administration (FDA) has granted priority review to AbbVie's supplemental new drug application for a new indication for Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir): to treat those with genotype 1b of the virus and compensated cirrhosis without ribavirin. The current dosing recommendation for this group is 12 weeks of Viekira Pak with ribavirin.

The FDA grants priority review status to investigational treatments for serious conditions that, if approved, would yield a significant improvement in safety or effectiveness. The status shortens the FDA's review period from the standard 10 months to six months, meaning a decision is expected in early July.

The application is based on the Phase IIIb TURQUOISE-III trial, in which 12 weeks of Viekira Pak without ribavirin cured 100 percent of participants with genotype 1b and compensated cirrhosis.

To read an AbbVie press release on the FDA application, click here.

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http://beta.docker.hepmag.com/article/Viekira-FDA-1b-28287-1377805658