Hepatitis C Treatments Viekira Pak and Technivie May Cause Liver Damage

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The U.S. Food and Drug Administration (FDA) has required AbbVie to change the labels for its two hepatitis C virus (HCV) treatments after receiving numerous reports of serious liver injury developing among people while taking the medications, Medscape reports.

Previously, the labels for Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir) and Technivie (ombitasvir/paritaprevir/ritonavir) stated the treatments were “not recommended” for those with Child-Pugh B liver disease and “contraindicated” for those with Child-Pugh C liver disease. The label will now state that both hep C treatments are contraindicated for those with moderate to severe liver impairment, specifically with Child-Pugh B or C liver disease.

Child-Pugh scores, which range from A to C, in order of severity, assess the prognosis of liver disease. A contraindication means that a drug should not be taken in specific circumstances, such as the existence of a health condition or if someone is taking another medication that conflicts with the drug.

Viekira Pak was approved to treat genotype 1 of hep C in December 2014 and Technivie was approved in July 2015 to treat those with genotype 4 of the virus who do not have cirrhosis. Since then, at least 26 worldwide cases have been submitted to the FDA Adverse Event Reporting System (FAERS) of liver injuries that possibly or probably were related to the two treatments.

In most of these cases, the liver damage occurred within the first 1 to 4 weeks of treatment. These individuals, who all had cirrhosis upon beginning treatment, developed decompensated cirrhosis, the more advanced form of the condition, or liver failure. Some of them underwent liver transplants, while others died. Some of the individuals were taking Viekira Pak or Technivie despite the fact that the drugs were contraindicated or not recommended for them given their personal circumstances.

The FDA has indicated that there may be more instances of these outcomes than have been reported to FAERS.

The FDA states that individuals taking either Viekira Pak or Technivie should contact a clinician immediately if they develop fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin (jaundice), or light-colored stools, which may indicate liver injury. The health agency

cautions individuals taking the therapies not to discontinue their use without first discussing the matter with a health professional, given that stopping treatment early may lead hep C to become resistant to other treatments and undermine future efforts to cure the virus.

Health care professionals, the FDA states, should closely monitor patients on Viekira Pak or Technivie for signs and symptoms of worsening liver disease, including ascites, hepatic encephalopathy, variceal hemorrhage, and increases in direct bilirubin in the blood.

In a release, AbbVie stated, “Viekira Pak, with and without ribavirin (RBV), remains indicated for genotype 1 HCV patients with compensated cirrhosis, including Child-Pugh A. The safety and efficacy of Viekira Pak, with and without RBV, has been studied in Phase III trials in more than 2,300 patients and is one of the recommended regimens in the [American Association for the Study of Liver Disease] guidelines for these patients. Technivie in combination with RBV is indicated for genotype 4 HCV patients without cirrhosis.”

To read an FDA release about the liver risks associated with Viekira Pak and Technivie, click here.

To read the Medscape article, click here (free registration with the site is required).

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