Immediate Release:
Serious Liver Injury with Hepatitis C Drugs

On August 28, 2019, the U.S. Food and Drug Administration (FDA) announced it had received reports that the use of Mavyret®, Zepatier® or Vosevi® to treat chronic hepatitis C in patients with moderate to severe liver impairment had resulted in rare cases of worsening liver function or liver failure.

Mavyret, Zepatier and Vosevi contain a hepatitis C virus (HCV) protease inhibitor and are not indicated for use in patients with moderate to severe liver impairment. Liver failure occurred in patients with signs and symptoms of moderate to severe liver impairment with a Child-Pugh B or C score who should not have been treated with these medications. Some cases had other significant pre-existing risk factors such as liver cancer, alcohol abuse or serious liver related illnesses. In most cases, liver failure occurred within the first 4 weeks of starting treatment. Symptoms resolved or liver function improved after stopping the medicine in most patients.

FDA-approval of Mavyret, Zepatier and Vosevi was based on clinical trials establishing safety and efficacy in patients with compensated cirrhosis or mild liver impairment. Due to the patient demographic studied, these drugs are indicated to treat chronic hepatitis C in patients without liver impairment or with mild liver impairment (Child Pugh A). These medicines act by reducing the amount of HCV in the body by preventing its replication, which can prevent or limit liver damage from HCV by clearing the virus from the body over time.

The risk of serious liver injury is rare, but healthcare professionals should be contacted if a patient on HCV therapy develops fatigue, weakness, loss of appetite, nausea or vomiting, yellow eyes or skin, or light-colored stools as these are signs of liver injury. These medicines have been widely used and are safe and effective in patients without liver impairment or in those with mild liver impairment for whom they are indicated.

To help the FDA track safety issues with medicines, report side effects involving Mavyret, Zepatier, Vosevi or other medicines to the FDA MedWatch program.

References

1. FDA flags risks from AbbVIE, Gilead, Merck hepatitis C drugs to certain patients. Available at: https://www.reuters.com/article/us-fda-hepatitis-c/fda-flags-risks-from-abbvie-gilead-merck-hepatitis-c-drugs-to-certain-patients-idUSKCN1VI2DU.
2. FDA warns about rare occurrence of serious liver injury with use of hepatitis C medicines Mavyret, Zepatier, and Vosevi in some patients with advanced liver disease. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrence-serious-liver-injury-use-hepatitis-c-medicines-mavyret-zepatier-and.
3. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.