FDA Approves Vemlidy for Adolescents With Hepatitis B

The antiviral treatment is safe and effective for pediatric patients ages 12 and up.

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The Food and Drug Administration (FDA) has approved the antiviral medication Vemlidy (tenofovir alafenamide, or TAF) for adolescents ages 12 and older with chronic hepatitis B, Gilead Sciences announced last week.

Although hepatitis B has declined among children and adolescents since the adoption of universal hepatitis B virus (HBV) vaccination for infants, those who do contract the virus can develop serious liver complications, including cirrhosis and liver cancer.

Vemlidy is a nucleoside analog drug that has demonstrated effectiveness against HBV in numerous studies of adults. It is less likely to cause kidney and bone side effects than the older tenofovir disoproxil fumarate (TDF, or Viread). TAF and TDF are both also widely used for HIV treatment and prevention (pre-exposure prophylaxis, or PrEP).

The FDA approved Vemlidy as a treatment for adults with chronic hepatitis B in 2016. Hepatitis B guidelines from the American Association for the Study of Liver Diseases and the European Association for the Study of the Liver recommend Vemlidy as a preferred or first-line therapy for adults with compensated liver disease, meaning the liver is still able to function.

The expanded indication covers pediatric patients ages 12 and older with compensated liver disease. The approval is supported by data from a Phase II clinical trial that included 70 adolescents ages 12 to 17 who were either receiving hepatitis B treatment for the first time or had previously tried other antivirals or interferon. Almost all were hepatitis B “e” antigen (HBeAg) positive, a group that’s more difficult to treat than those with HBeAg-negative disease.

The study compared a 25-milligram dose of Vemlidy once daily versus a placebo. One in five children (21%) treated with Vemlidy achieved an undetectable HBV viral load (HBV DNA below 20 IU/mL) after six months of treatment, compared with none in the placebo group. What’s more, 44% of Vemlidy recipients, but no placebo recipients, experienced ALT liver enzyme normalization, indicating reduced liver inflammation.

[Update: the virological response rate for adolescents rose to 40% at 48 weeks and 64% at 96

weeks.]

This is substantial lower than virological response rates for adults with chronic HBV, which are around 90% for HBeAg-negative people and around 60% for those who are HBeAg positive. Antiviral treatment for hepatitis B seldom leads to a cure.

Vemlidy is taken as a pill once daily. It is generally safe and well tolerated; the most common adverse reaction is headache. The product label warns that people who stop taking antivirals can experience severe hepatitis flare-ups, so liver function should be monitored closely if Vemlidy is discontinued.

“As a clinician, I recognize the critical importance of treating this disease as quickly as possible to help avoid complications and potential damage to the liver,” study investigator Kathleen Schwarz, MD, of Rady Children’s Hospital in San Diego, said in a Gilead press release. “In the clinical trial, we saw that tenofovir alafenamide may represent an effective treatment option for people as young as 12 years of age living with this chronic disease.”

Click here for full prescribing information for Vemlidy.
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