Viread Receives Second Approval for Hep B Infection

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Gilead Sciences announced earlier this week that the U.S. Food and Drug Administration has approved Viread (tenofovir) for the treatment of chronic hepatitis B virus (HBV) infection, a leading cause of liver cancer among HIV-positive and HIV-negative people. Although Viread is not specifically approved to treat HBV in people living with HIV, health care providers frequently prescribe tenofovir—often used as Truvada or Atripla, which also contain emtricitabine, another antiretroviral (ARV) with activity against HBV—to treat both infections at the same time.

Viread works against hepatitis B by blocking HBV's polymerase, the enzyme that is necessary for the virus to reproduce, or replicate, in liver cells. The drug was originally approved to treat HIV infection in 2001.

The approval of Viread for chronic HBV is based on data from two ongoing clinical trials comparing Viread to another Gilead drug approved specifically for hepatitis B: Hepsera (adefovir). Forty-eight week results from both studies showed that a significantly greater percentage of patients with chronic HBV who received Viread achieved a complete response to treatment compared with those who received Hepsera.

A complete response was defined as HBV viral load below 400 copies and an improvement of liver inflammation with no worsening of fibrosis (scarring of the liver). Study participants included both HIV-negative patients new to HBV therapy and patients who had received previous nucleoside treatment.

A clinical trial comparing Viread to Hepsera in HIV-infected patients, published in 2006, demonstrated benefits of Viread when treating HBV resistance to Epivir (lamivudine)—another ARV used to treat HIV and an early oral medication used to treatment HBV.

Because there is significant overlap between the drugs used to treat HIV and HBV—which can

make things much easier—it is often necessary to carefully consider when to start therapy for both infections and which medications to use. For example, HIV-negative patients with HBV may hold off on starting therapy until they have a high HBV viral load and abnormal liver enzyme levels. However, according to guidelines drafted by the U.S. Department of Health and Human Services (DHHS), people infected with both HIV and HBV starting ARV treatment should also be treated for HBV, regardless of their HBV viral loads. DHHS recommends that they receive treatment with medications active against both HIV and HBV—tenofovir-containing medications such as Viread, Truvada or Atripla, for example—or with medications with independent activity against each virus.

Viread was approved for treating chronic HBV in the European Union, Turkey, Australia and New Zealand earlier this year, and a marketing application is currently pending in Canada.

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