FDA Declines Approval of First Hepatitis D Treatment

The agency cited manufacturing concerns but did not question the safety and effectiveness of bulevirtide.

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The Food and Drug Administration (FDA) has declined to approve bulevirtide, which would have been the first authorized treatment for hepatitis D, a virus that can accompany and worsen the complications of hepatitis B.

The FDA issued a Complete Response Letter to Gilead Sciences last week, citing concerns regarding the manufacture and delivery of the drug. However, the agency did not question the safety and effectiveness of bulevirtide or request further clinical trials, according to a company statement.

Bulevirtide is a first-in-class entry inhibitor that binds to surface receptors that the hepatitis B virus (HBV) uses to enter liver cells. The hepatitis D virus (HDV; also known as hepatitis delta) is a defective virus that can only replicate in the presence of HBV. By interfering with the HBV lifecycle, the drug also prevents HDV replication.

Over time, chronic hepatitis B can cause liver fibrosis, cirrhosis and liver cancer. Coinfection with both HBV and HDV leads to more rapid and severe liver disease progression. Although only around 5% of people with HBV also have HDV, according to the World Health Organization, coinfection contributes to a disproportionate share of advanced liver disease and mortality. Coinfection is more common among people who also have hepatitis C or HIV.

Hepatitis B can be prevented with a vaccine, which also prevents hepatitis D. Antiviral medications can suppress HBV replication as long as treatment continues, but they seldom lead to a cure. So far, there are no treatments specifically approved for hepatitis D in the United States.

The European Medicines Agency—the European Union's counterpart to the FDA—approved bulevirtide, marketed as Hepcludex, in August 2020. The drug is also approved in Russia, where it is sold as Myrcludex. In 2018, the FDA granted bulevirtide a breakthrough therapy designation, intended to speed up the approval of therapies for serious conditions with no satisfactory existing treatment. Last year, Gilead acquired Myr GmbH, the company that developed bulevirtide.

According to Gilead chief medical officer Merdad Parsey, MD, PhD, the company will work with the FDA to address the agency's concerns and plans to resubmit a biologics license application for bulevirtide as quickly as possible. "While we are disappointed with this outcome, we remain confident in the benefits bulevirtide could potentially bring to people living with HDV in the U.S.," he said. "Today's news does not change the safety and efficacy profile observed in clinical trials to date."

This confidence is supported by promising study results presented at medical conferences over the past several years. Bulevirtide has been found to be safe and generally well tolerated in clinical trials so far. Data presented at this year's International Liver Congress showed that the drug suppressed HDV production, decreased liver inflammation biomarkers and lessened liver fibrosis. After 48 weeks of treatment, 45% of people who received a 2-milligram dose of bulevirtide and 48% of those who received a 10-mg dose achieved both HDV viral load reduction and ALT liver enzyme normalization. What's more, participants treated with bulevirtide reported improved quality of life.

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