FDA Approves Hepcludex as First Hepatitis D Treatment

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On May 22, the Food and Drug Administration (FDA) granted accelerated approval of Hepcludex (bulevirtide) for hepatitis D, the first and only specific treatment to get the green light in the United States.

Hepatitis D, or delta, virus (HDV) is a defective virus that can replicate only in the presence of hepatitis B virus (HBV). Over time, chronic hepatitis B can cause cirrhosis, liver cancer and end-stage liver failure; dual infection with both HBV and HDV leads to more rapid and severe liver disease progression. In the United States, an estimated 2% to 4% of people with chronic hepatitis B—or around 40,000 to 80,000 individuals—also have HDV. HBV/HDV coinfection is more common among people who also have hepatitis C or HIV.

“Today’s approval fills a critical gap in care for patients with chronic HDV infection, who until now have had no FDA-approved therapies available,” Wendy Carter, DO, acting director of the Office of Infectious Diseases in the FDA’s Center for Drug Evaluation and Research, said in a news release. “For individuals living with this chronic viral infection, this new treatment option offers hope in managing a disease that can rapidly progress to serious liver complications.”

Hepcludex is a first-in-class entry inhibitor that binds to surface receptors and blocks HBV and HDV from entering liver cells. By interfering with the HBV lifecycle, the drug also prevents HDV replication. In 2021, Gilead Sciences acquired Myr GmbH, the company that initially developed bulevirtide.

In clinical trials, people who received Hepcludex alone or in combination with HBV antivirals or pegylated interferon were more likely to have undetectable HDV in their blood and liver. Studies have also shown that Hepcludex can reduce liver enzyme levels and improve fibrosis. In the Phase III MYR301 trial (NCT03852719), 48% of participants randomized to start Hepcludex immediately achieved a combined endpoint of undetectable or substantially reduced HDV RNA and ALT normalization at 48 weeks, compared with 2% of those who delayed treatment. Some research indicates that the drug can sometimes lead to a functional cure, or sustained viral suppression after stopping treatment.

The European Medicines Agency—the European Union's counterpart to the FDA—approved Hepcludex in August 2020; bulevirtide is also approved in Russia under the brand name Myrcludex. In 2018, the FDA gave it a breakthrough therapy designation, intended to speed up approval of therapies for serious conditions with no satisfactory existing treatment.

In November 2022, however, the FDA declined to approve Hepcludex, citing manufacturing and delivery concerns. The agency did not question the drug's safety and effectiveness or request further clinical trials. Gilead said it would address the FDA's concerns and resubmit a licensing application as quickly as possible, but more than three years elapsed without further news about the drug's progress until last week.

Hepcludex was approved for adults with chronic HDV infection who either do not have cirrhosis or have compensated cirrhosis. That is, it is not indicated for those with severe, or decompensated, cirrhosis. Therapies that receive FDA accelerated approval are expected to undergo further testing to determine whether they offer clinical benefits, and the agency can rescind the approval is they fail to measure up.

"For patients, an HDV diagnosis means managing two distinct viral liver diseases—hepatitis B and hepatitis D—each contributing to disease progression, monitoring demands and treatment complexities," Ira Jacobson, MD, of NYU Grossman School of Medicine, said in a Gilead news release. "The approval of Hepcludex for chronic HDV represents a critical advancement, introducing a long-awaited option that begins to address a significant unmet medical need and has the potential to meaningfully alter the course of this devastating disease for people living with HDV in the United States."

Hepcludex is given as a once-daily subcutaneous injection that can be self-administered in the thigh or abdomen. It can be used along with other medications for hepatitis B, such as Viread (tenofovir disoproxil fumarate), Vemlidy (tenofovir alafenamide) or Baraclude (entecavir). Treatment can last for as long as it continues to suppress viral replication. Hepcludex is generally safe and well tolerated. The drug's prescribing information includes a warning that discontinuation can lead to worsening liver disease. Gilead did not announce a price for Hepcludex, but in Canada, it exceeds $100,000 per year.

"Until now, there was very little that we could do to prevent cirrhosis and liver cancer for people living with hepatitis delta in the U.S.," Hepatitis B Foundation president Chari Cohen, DrPH, MPH, said in a news release. "All of us at the Hepatitis B Foundation are optimistic that the FDA's approval of Hepcludex will be a game changer, leading to improved HDV screening, diagnosis, care and treatment across the U.S."

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