Gilead’s drug wins first-ever US approval for deadly liver infection

The U.S. Food and Drug Administration approved the drug, Hepcludex, to treat chronic hepatitis delta virus, or HDV, a liver disease that affects only people already infected with hepatitis B and can lead to scarring, cancer, organ failure and death.

Bengaluru: Gilead Sciences said on Friday that its experimental drug for a rare and deadly liver infection that had no approved treatment has won U.S. approval.

Shares of the company were up over 2% in afternoon trading.

The U.S. Food and Drug Administration approved the drug, Hepcludex, to treat chronic hepatitis delta virus, or HDV, a liver disease that affects only people already infected with hepatitis B and can lead to scarring, cancer, organ failure and death.

In the United States, an estimated 40,000 to 80,000 people are living with the disease, according to the company.

"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," said Wendy Carter, acting director of the Office of Infectious Diseases in FDA's Center for Drug Evaluation and Research.

The approval was based on a late-stage trial, in which about 48% of patients who received the treatment showed a meaningful improvement after 48 weeks, compared with 2% of those whose treatment was delayed. The virus became undetectable in patients the longer they remained on Hepcludex, the trial showed.

Hepcludex, given as a once-daily injection, works by blocking the virus from entering liver cells, slowing the spread of infection.

The health regulator approved the drug through its accelerated approval pathway, which is designed to fast-track treatments for serious diseases with few or no alternatives.

Gilead has committed to a longer-term study to confirm the drug's full clinical benefit.

The drug carries the FDA's most serious warning, called a boxed warning, alerting that stopping treatment can trigger severe, potentially life-threatening flare-ups of both hepatitis D and hepatitis B, particularly in patients with advanced liver scarring.

A different dose of the drug was granted full approval in Europe in 2023.

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