US FDA approves Gilead's twice-yearly injection for HIV prevention

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By Deena Beasley and Julie Steenhuysen

Los Angeles: The U.S. Food and Drug Administration on Wednesday approved Gilead Sciences lenacapavir, a twice-yearly injection, for preventing HIV infection in adults and adolescents at high risk of contracting the deadly virus.

Investors and AIDS activists had been eagerly awaiting the regulatory decision for the drug seen as convenient enough to help end the 44-year-old HIV epidemic.

It will be sold under the brand name Yeztugo in the U.S. at a list price of $28,218 a year.

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Yeztugo "will only be as effective as it is accessible and affordable," Kevin Robert Frost, CEO of the Foundation for AIDS Research, said in a statement, calling on Gilead and the U.S. government to make sure people who want lenacapavir can get it.

Gilead said it is working to secure health insurer coverage. It said it will provide co-pay assistance for eligible insured people, and the drug may be available free of charge for some under its program for the uninsured.

Medications to prevent HIV, known as pre-exposure prophylaxis, or PrEP, are widely available. But most are daily pills, including low-cost generic versions of Gilead's older drug Truvada, that require strict adherence to be effective. Gilead said Yeztugo is priced in line with other branded drugs.

"This is a milestone moment," said Gilead Chief Executive Daniel O'Day of the approval.

"We believe that lenacapavir is the most important tool we have yet to bend the arc of the epidemic and move this epidemic into the history books," O'Day said.

Availability of a twice-yearly HIV prevention tool is "a huge advance," that could help change the course of the epidemic, Dr. Raphael Landovitz, director of the UCLA Center for Clinical AIDS Research & Education, said in an email. But he said the product's high launch price "is almost certainly going to complicate payor coverage and access."

Gilead has plans for a rapid launch in the United States as well as a wider rollout of the drug in collaboration with global partners.

Gilead's chief commercial officer, Johanna Mercier, said the company's "end game" is to normalize PrEP usage, both in the United States and other countries, including low-income African nations where the virus is most prevalent.

Citi Research analyst Geoff Meacham said he expects Yeztugo's launch to be slow and steady, reaching annual sales of $2.8 billion by 2030.

Mercier said she expects around 75% of U.S. insurers, including government health plans, will cover lenacapavir for PrEP within about six months, with the number rising to 90% within 12 months of launch.

The drug is currently sold as a treatment in the U.S. under the brand name Sunlenca for patients with advanced disease that has become resistant to other drugs.

PEPFAR CUTS

In December, the President's Emergency Plan for AIDS Relief (PEPFAR) under then-President Joe Biden signed an agreement with the Global Fund to Fight AIDS, Tuberculosis and Malaria to provide the treatment to as many as 2 million people for three years if it won U.S. regulatory approval for prevention.

That would allow for unprecedented early access to a state-of-the-art treatment, as six generic drugmakers that have licensed the product from Gilead gear up for production of low-cost versions in 120 resource-limited countries.

AIDS activists have viewed the drug as a way to significantly slow the epidemic, but cuts to PEPFAR by the Trump administration have raised concerns about the U.S. government's commitment to the rollout.

O'Day acknowledged that the changes have been "challenging," but said the company has continued to have discussions with both the Global Fund and PEPFAR.

"I believe that there will be sources of funding for this, and that these organizations will prioritize this type of prevention," he said. (Reporting by Deena Beasley in Los Angeles and Julie Steenhuysen in Chicago; Editing by Bill Berkrot and Leslie Adler)

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