

US FDA approves Gilead's once-daily combination pill for HIV treatment

The drug, branded Bixlenvo, combines Gilead's HIV medicines bicitegravir and lenacapavir.



Bengaluru: The U.S. Food and Drug Administration has approved Gilead Sciences' once-daily oral combination pill for treatment of adults whose HIV infection has already been reduced to very low levels, the company

said on Thursday.

The drug, branded Bixlenvo, combines Gilead's HIV medicines bicitegravir and lenacapavir.

The wholesale acquisition cost for a 30-day supply of Bixlenvo is \$4,595, a Gilead spokesperson told Reuters.

Bicitegravir, the key component of the blockbuster treatment Biktarvy, is a widely recommended HIV drug with a high barrier to resistance.

Lenacapavir, marketed as Sunlenca for HIV treatment and as Yeztugo for HIV prevention, is a capsid inhibitor that targets the virus's protective shell to disrupt its multiplication.

Patients must take an initial two-day dose of Sunlenca, before taking Bixlenvo once daily. Gilead expects Bixlenvo to become available within days of approval.

The human immunodeficiency virus (HIV) attacks the body's immune system. Without treatment, it can lead to AIDS. There is currently no effective cure.

"The main advantage of this combination is that it potentially offers a simpler option, in terms of pill burden, to patients who might currently be on more complex regimens due to a history of drug resistant virus," said Monika Shah, an infectious disease specialist at Memorial Sloan Kettering Cancer Center.

The approval was based on two late-stage studies in which Bixlenvo was as effective as complex multi-pill regimens or Biktarvy in keeping the virus suppressed after 48 weeks.

Bixlenvo is part of Gilead's multi-year strategy to expand its HIV portfolio, grounded in lenacapavir, Jared Baeten, the company's head of clinical development for virology, told Reuters. About 5% of people living with HIV in the United States take complex regimens involving more than one tablet a day, Baeten said.

The combination enters a competitive HIV-treatment market that includes Merck's Idvynso, a once-daily two-drug pill approved in April for certain adults whose HIV-1 is already suppressed.

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