

US FDA approves Merck's pill combo to treat HIV infection

The two-drug combination of doravirine and islatravir, branded as Idvynso, was approved to replace the current antiretroviral regimen for treating Human Immunodeficiency Virus-1 infection in some adults.



Bengaluru: The U.S. Food and Drug Administration has approved Merck's once-daily, oral, combination regimen for HIV infections, the drugmaker said on Tuesday, giving patients

another treatment option to manage the condition.

The two-drug combination of doravirine and islatravir, branded as Idvynso, was approved to replace the current antiretroviral regimen for treating Human Immunodeficiency Virus-1 infection in some adults.

While islatravir is an experimental treatment, Merck's doravirine is approved and sold in the U.S. under the brand name Pifeltro for HIV-1 treatment in combination with other antiretrovirals, and as a single-tablet regimen, Delstrigo.

HIV-1 is the most common strain of the retrovirus that causes acquired immunodeficiency syndrome, commonly known as AIDS.

About 40.8 million people are living with HIV globally, and about 1.3 million new infections occur annually, according to National Institutes of Health data.

"Idvynso expands therapeutic diversity beyond the currently available oral treatment options," said Dr. Eliav Barr, senior vice president and chief medical officer, Merck Research Laboratories.

In two late-stage studies with more than 1,000 patients, the treatment combination met the main goal of significantly suppressing replication of HIV-1 in adults receiving another form of therapy.

Last year, Merck's oral drug combination was found to be non-inferior to Gilead's top-selling drug, Biktarvy, achieving similar HIV-1 suppression to the current standard of care.

While this is a meaningful developmental milestone for Merck, RBC Capital Markets analyst Trung Huynh expects initial commercial impact to be limited, with the inflection point being a potential approval in patients who have not received any treatment.

Merck's HIV story is best viewed as a "multi-year build rather than a near-term growth driver," said Huynh.

Islatravir is being tested in multiple trials in combination with other antiretrovirals for potential daily and once-weekly treatments for HIV-1.

News Source:

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