

# US approves new once-a-day pill to treat HIV (Update)

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A new pill to treat HIV infection—combining two previously approved drugs plus two new ones—has been approved for adults living with the virus that causes AIDS, US regulators said Monday.

The single daily dose of Stribild provides a complete treatment regimen for HIV infection, the US Food and Drug Administration said in a statement, and is meant for people who have not already received treatment with other HIV drugs.

"Through continued research and drug development, treatment for those infected with HIV has evolved from multi-pill regimens to single-pill regimens," said Edward Cox, director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research.

"New combination HIV drugs like Stribild help simplify treatment regimens."

The new pill, previously called Quad, is made by Gilead Sciences in California and "should be available to patients by the end of the week," company spokeswoman Erin Rau told AFP.

The company said it tested the pill in two double-blind clinical trials of more than 1,400 patients.

Results showed that Stribild performed as well or better than two other treatment combinations, and brought virus readings down to

undetectable levels in around nine of 10 patients after 48 weeks.

"Therapies that address the individual needs of patients are critical to enhancing adherence and increasing the potential for treatment success," Gilead chief John Martin said in a company statement.

But some advocates say the new pill is priced far too high.

"We wanted to see (a price of) no more than the current drug," said Michael Weinstein, president of the AIDS Healthcare Foundation, referring to Gilead's previously approved three-in-one pill, Atripla. But he said the price will be about a third higher than the three-pill combo.

The new drug "is not a significant improvement over existing therapies," Weinstein told AFP, adding the cost will "severely limit access" to the new medication.

Gilead is charging wholesalers \$28,500 a year for the drug, but said it will provide discounts to state assistance programs and has created a patient financial-assistance program, Rau said.

This is Gilead's third single-tablet anti-HIV combination therapy, the company noted, adding it is still seeking approval for the newest offering in Australia, Canada and the European Union.

To get the drug to HIV patients in the developing world, where millions lack access to effective treatment options, generic versions are being developed—with permission and help from Gilead—by a number of Indian manufacturers and the Medicines Patent Pool, a non-profit that helps facilitate generic drug-making.

The drug combines Truvada—another Gilead offering approved in 2004, that combines emtricitabine and tenofovir disoproxil fumarate to fight

an enzyme that HIV needs to replicate—with elvitegravir, another enzyme-fighting drug, and cobicistat, which enhances the effects of elvitegravir.

The FDA said further study is required to determine the quad-drug's safety for women and children, how resistance may develop, and whether the drug interacts with other drugs.

Stribild will also be required to carry a label warning patients and health care providers the drug can cause fatal side effects, including severe liver problems, and a build-up of lactic acid in the blood. The FDA said the label is also required for many other HIV-fighting drugs.

But Gilead said that during the studies, "most adverse effects were mild to moderate." The FDA said patients commonly experienced nausea and diarrhea.

The drug also weakened bones and caused or worsened kidney problems—both of which will be mentioned in a warning on the drug's label.

Truvada was previously approved as a treatment for people infected with HIV to be used in combination with other antiretroviral drugs.

In July, it was also approved for use by healthy at-risk adults to prevent HIV, the first-ever daily pill approved for that purpose.

This year, the FDA also approved the first rapid HIV test that can be bought without a prescription and taken at home.

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