

FDA review favors first drug for HIV prevention (Update)

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This photo provided by Gilead Sciences shows Truvada. Federal drug regulators on Tuesday affirmed landmark study results showing that a popular HIV-fighting pill can also help healthy people avoid contracting the virus that causes AIDS in the first place. While the pill appears safe and effective for prevention, scientists stressed that it only works when taken on a daily basis. The Food and Drug Administration will hold a meeting Thursday to discuss whether Truvada should be approved for people who are at risks of contracting HIV through sexual intercourse. The agency's positive review posted Tuesday suggests the daily pill will become the first drug approved to prevent HIV infection in high-risk patients. (AP Photo/Gilead Sciences)

(AP) -- A pill that has long been used to treat HIV has moved one step closer to becoming the first drug approved to prevent healthy people from becoming infected with the virus that causes AIDS.

The Food and Drug Administration said Tuesday that Gilead Sciences' Truvada appears to be safe and effective for HIV prevention. It concluded that taking the pill daily could spare patients "infection with a serious and life-threatening illness that requires lifelong treatment."

On Thursday a panel of FDA advisers will consider the review when it votes on whether Truvada should be approved as a preventative treatment for people who are at high risk of contracting HIV through sexual intercourse. The FDA is not required to follow the advice of its panels, but it usually does.

An estimated 1.2 million Americans have HIV, which attacks the immune system and, unless treated with antiviral drugs, develops into AIDS, a fatal condition in which the body cannot fight off infections. If Truvada is approved, it would be a major breakthrough in the 30-year campaign against the AIDS epidemic. There have been no other drugs proven to prevent HIV and a vaccine is believed to be decades away.

Gilead Sciences Inc., based in Foster City, Calif., has marketed Truvada since 2004 as a treatment for people who are infected with the virus. The medication is a combination of two older HIV drugs, Emtriva and Viread. Doctors usually prescribe the medications as part of a drug cocktail that makes it harder for the virus to reproduce. Patients with low viral levels have reduced symptoms and are far less likely to develop AIDS.

Researchers first reported that Truvada could prevent people from contracting HIV in 2010. A three-year study found that daily doses cut the risk of infection in healthy gay and bisexual men by 44 percent, when accompanied by condoms and counseling. Another study found that Truvada reduced infection by 75 percent in heterosexual couples in which one partner was infected with HIV and the other was not.

Because Truvada is already on the market to manage HIV, some doctors already prescribe it as a preventive measure. But FDA approval would allow the drugmaker Gilead Sciences to formally market its drug for that use.

FDA reviewers on Tuesday said that patients must be diligent about taking the pill every day if using it as a preventative measure. Adherence to the medication was less than perfect in clinical trials, and reviewers said that patients in the real world may forget to take their medication even more than those in clinical studies.

Some patient advocacy groups say the drug is an important new option to prevent HIV, alongside condoms, counseling and other measures. Last month, advocacy group AIDS United and more than a dozen other groups sent a letter to the FDA, urging approval of Truvada.

"If we're going to reduce the more than 50,000 new HIV infections in this country each year, we need to increase the available options for people," said Ronald Johnson, AIDS United's vice president.

But support for FDA approval is not unanimous.

Although the FDA is legally barred from considering cost when reviewing drugs, health care providers have raised concerns about Truvada's price tag: \$900 a month, or just under \$11,000 per year. Medicare and Medicaid, the nation's largest health insurance plans, generally cover drugs approved by the FDA, and analysts expect most large health insurers to follow suit.

Additionally, some researchers say the prevention pill is not the chemical equivalent of condoms, which they say remain the best weapon against AIDS. They also worry about Truvada's mixed success rate in preventing infection among women: Last year, a study in women was stopped early

after researchers found that women taking the drug were more likely to become infected than those taking placebo.

Researchers speculated that women may require a higher dose of the drug to prevent infection. They also said the disappointing results may have resulted from women not taking the pills consistently.

"We know that if the person doesn't take the medication every day they will not be protected," said Dr. Rodney Wright, director of HIV programs at Montefiore Medical Center in New York and chairman of the AIDS Health Foundation. "So the concern is that there may not be adequate adherence to provide protection in the general population."

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