MedicalXpress

US approves first pill to help prevent HIV

July 16 2012, by MATTHEW PERRONE

(AP) — The Food and Drug Administration on Monday approved the first drug shown to reduce the risk of HIV infection, the latest milestone in the 30-year battle against the virus that causes AIDS.

The agency approved Gilead Sciences' pill Truvada as a preventive measure for healthy people who are at high risk of acquiring HIV through sexual activity, such as those who have HIV-infected partners. The decision comes less than two weeks after the agency approved another landmark product: the first over-the-counter HIV test that Americans can use in the privacy of their homes.

The two developments are seen as the biggest steps in years toward curbing the spread of HIV in the U.S., which has held steady at about 50,000 new infections per year for the last 15 years. An estimated 1.2 million Americans have HIV, which develops into AIDS unless treated with antiviral drugs. And it's estimated that one-fifth, or about 240,000 people, are unaware that they are infected.

"I think the combination of self-testing and a medicine that you can take at home to prevent infection could mean a whole new approach to HIV prevention that is a bit more realistic," said Dr. Demetre Daskalakis of New York University's Langone Medical Center, who served on the FDA panel that recommended approving Truvada. While a positive step forward, Daskalakis added that Truvada would likely be unavailable for many people without health insurance, who often face the greatest risk of acquiring HIV.

Researchers had long sought to create a pill that could help stem the epidemic. Public health advocates said Monday that Truvada represents a major breakthrough, both as a medical therapy and as a means of expanding other preventive measures. Patients who get a prescription for Truvada will be expected to take part in a comprehensive HIV prevention plan, which experts say will enhance the drug's impact.

"It really marks a new era in HIV prevention because in adding Truvada as a prevention strategy, what comes with it is expanded access to HIV testing, condoms and preventive counseling and support," said James Loduca, vice president of the San Francisco AIDS Foundation.

But HIV experts have raised concerns that patients might not use the drug correctly. Dr. Tom Giordano of Baylor College of Medicine said Monday the drug must be taken every day to be effective, and would be most effective for a relatively small group of people.

"It's been most effective in people who are at very high risk and are able to take the drug on a regular basis," said Giordano, who served on the FDA panel that recommended approving the drug. "When you really boil it down that's going to be a relatively focused population, but it's an important population to treat."

The drug's label carries a warning that people should be tested to make sure they don't have HIV before starting Truvada. Patients who already have the virus could develop resistance to the drug, making their disease more difficult to treat. The label also warns of side effects, including kidney and liver problems.

Gilead Sciences Inc. has marketed Truvada since 2004 as a treatment for people who are already infected with the virus. The once-a-day pill is a combination of two older HIV drugs, Emtriva and Viread.

Starting in 2010, studies showed that the drug could prevent people from contracting HIV when used as a precautionary measure. A three-year study found that daily doses cut the risk of infection in healthy gay and bisexual men by 42 percent, when accompanied by condoms and counseling. Last year, 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 on the market to manage HIV, some doctors already prescribe it as a preventive measure. FDA approval will allow Gilead Sciences to formally market the drug for that use, which could dramatically increase prescriptions.

Truvada's groundbreaking preventive ability has exposed disagreements about managing the disease among those in the HIV community. Groups including the AIDS Healthcare Foundation asked the FDA to reject the new indication, saying it could give patients a false sense of security and reduce the use of condoms, the most reliable preventive measure against HIV.

But FDA scientists said Monday said there was no indication from clinical trials that Truvada users were more likely to engage in risky sexual behavior.

"What we found was that condom use increased over time and sexually transmitted infections either remained at baseline levels or decreased," said Dr. Debra Birnkrant, FDA's director of antiviral products. "So in essence, we don't have any strong evidence that condoms were not used or there was a decrease in condom use."

Gilead Sciences said Monday that it would keep the pill at its current price, nearly $14,000 per year. Even at that price, HIV physicians said the drug could be cost effective if it prevents people from contracting

the virus.

"It is expensive, but on the other hand it's far cheaper than a lifetime of HIV treatment," said Dr. Joel Gallant of Johns Hopkins University School of Medicine. "So if there are people who will not use condoms but are willing to use this, then for those people it's cost effective."

The lifetime cost of treating one person diagnosed with the AIDS virus has been estimated at more than $600,000.

The decision by the FDA on Truvada follows its approval of the OraQuick test earlier this month. The test, which detects the presence of HIV in saliva collected using a mouth swab and returns a result within 40 minutes, is aimed at people who might not otherwise be tested. The FDA has said the test is not 100 percent accurate.