AIDS fight enters new phase with prevention pill

May 11 2012, By LINDSEY TANNER , AP Medical Writer

In this Thursday, May 10, 2012 photo, Dr. Lisa Sterman holds up a Truvada pill at her office in San Francisco. Sterman prescribes the drug off-label for about a dozen patients at high risk for developing AIDS. The pill, already used to treat people with HIV, also helps prevent the virus from infecting healthy people. The Food and Drug Administration is expected to decide by June 15 whether the pill's maker Gilead Sciences should be allowed to formally market the drug for preventive use. (AP Photo/Jeff Chiu)

(AP) -- Condoms and other safe-sex practices have accomplished only so much. Now the 30-year battle against AIDS is on the verge of a radical new phase, with the government expected to endorse a once-a-day pill to prevent infection with the virus.

Some doctors are already giving patients the drug, Truvada, to ward off infection. But Food and Drug Administration approval would expand

that practice and could make the highly expensive medicine more affordable. Truvada costs around $11,000 to $14,000 a year.

Approval seems likely after an FDA advisory panel Thursday endorsed the use of Truvada for prevention.

In the generation-long fight against AIDS, "it's the first time we have talked about a medication for prevention of HIV," said Dr. Lisa Sterman of Francisco, who treats HIV-positive patients.

"With this recommendation, we're nearing a watershed moment in our fight against HIV," said James Loduca, a spokesman for the San Francisco AIDS Foundation. "We know this isn't a magic bullet, and it's not going to be the right prevention strategy for everyone, but it could save thousands of lives in the United States and potentially millions around the world."

Truvada has been FDA-approved since 2004 for treating people infected with the AIDS virus. Once a drug is on the market, doctors are free to prescribe it for off-label, or unapproved, uses, and that's what some have been doing in giving Truvada to patients who are healthy but in danger of getting the virus from their partners or through risky sex.

Official FDA backing of the practice would allow Truvada's maker, Gilead Sciences Inc. of Foster City, Calif., to market it for prevention. Approval would also probably lead many more insurance companies to pay for the drug. And by widening the market for Truvada, it could prompt Gilead to lower the price.

An FDA decision is expected by June 15.

The FDA is also considering approving the first over-the-counter HIV test for use at home. Experts said it could help slow the spread of HIV.

An estimated 1.2 million Americans and millions more around the world have HIV. Unless the virus is treated with antiviral drugs, it can turn into full-blown AIDS. Antivirals have made the disease more manageable and allowed patients to live much longer than when the epidemic began in the early 1980s.

Nevertheless, about 50,000 new infections are diagnosed in the U.S. each year, a number that has held steady for about 15 years.

Truvada represents "a pretty radical step, but I think it's a necessary step," said Sterman, who prescribes it to infected patients and those who are healthy but at risk. "We've come as far as we can with condom use and safe-sex strategies."

In one U.S. government-run study of more than 1,200 men and women in Botswana, Truvada lowered the HIV infection risk by about 78 percent. Another larger study in Africa found a slightly lower rate of effectiveness, but researchers say that if used as directed, the pill can be 90 percent effective or higher.

It is available as an HIV treatment in Africa and other poor regions, but Gilead is seeking approval for prevention in the U.S. only, a company spokeswoman said. Some experts have expressed concern that the use of Truvada for prevention could cause shortages in poor countries that desperately need the drug to treat infected people.

Not everyone in the HIV community is gung-ho about the drug.

Michael Weinstein, president of the AIDS Healthcare Foundation, a Los Angeles-based group that calls itself the nation's largest provider of medical care for HIV, said his main concern is that patients won't take the drug as directed - once a day, while also using condoms. Misuse could create drug-resistant HIV strains and lead to more infections.

The FDA panelists acknowledged that concern and said 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.

Sterman said shortages in the U.S. are unlikely because the drug would be recommended only for people at high risk of getting the virus. That could include gay men with multiple sex partners, prostitutes and people whose partners are infected.

"I don't think demand for it is going to be that high," she said.

As for the drug's high cost, generic Truvada for HIV treatment is available in poor countries for as little as $9 per month, a Gilead spokeswoman said. But generic versions are not available in the United States and won't be until after Truvada's U.S. patent expires in 2021. Sterman said she hopes FDA approval leads Gilead to lower the price.

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

"It's much more cost-effective to prevent a new infection than it is to treat someone for their lifetime," Loduca said. "Of course, the ultimate goal is a vaccine and a cure, but we're many years away from that."

Some of the more serious complications linked to Truvada include kidney and liver problems. But for some people, the risk of kidney problems "10 years down the line may be less than the risk for acquiring HIV, which is significantly more problematic and can be fatal," said Jim Pickett, director of prevention advocacy at the AIDS Foundation of Chicago.

More information: FDA: http://www.fda.gov

AIDS: http://www.aids.gov