FDA NEWS RELEASE

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FDA approves first drug for reducing the risk of sexually acquired HIV infection

Evidence-based approach enhances existing prevention strategies

Today, the U.S. Food and Drug Administration approved Truvada (emtricitabine/tenofovir disoproxil fumarate), the first drug approved to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and who may engage in sexual activity with HIV-infected partners. Truvada, taken daily, is to be used for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually-acquired HIV infection in adults at high risk.

The FDA previously approved Truvada to be used in combination with other antiretroviral agents for the treatment of HIV-infected adults and children 12 years or older.

As part of PrEP, HIV-uninfected individuals who are at high risk will take Truvada daily to lower their chances of becoming infected with HIV should they be exposed to the virus. A PrEP indication means Truvada is approved for use as part of a comprehensive HIV prevention strategy that includes other prevention methods, such as safe sex practices, risk reduction counseling, and regular HIV testing.

"Today's approval marks an important milestone in our fight against HIV," said FDA Commissioner Margaret A. Hamburg, M.D. "Every year, about 50,000 U.S. adults and adolescents are diagnosed with HIV infection, despite the availability of prevention methods and strategies to educate, test, and care for people living with the disease. New treatments as well as prevention methods are needed to fight the HIV epidemic in this country."

As a part of this action, the FDA is strengthening Truvada's Boxed Warning to alert health care professionals and uninfected individuals that Truvada for PrEP must only be used by individuals who are confirmed to be HIV-negative prior to prescribing the drug and at least every three months during use. The drug is contraindicated for PrEP in individuals with unknown or positive HIV status. The FDA strongly recommends against such use.

Truvada for PrEP is being approved with a Risk Evaluation and Mitigation Strategy (REMS) to minimize the risk to uninfected individuals of acquiring HIV infection and to reduce the risk of development of resistant HIV-1 variants. The central component of this REMS is a training and education program to assist prescribers in counseling individuals who are taking or considering Truvada for PrEP. The training and education program will not restrict distribution of Truvada but will provide information about the importance of adhering to the recommended dosing regimen and understanding the serious risks of becoming infected with HIV while taking Truvada for the PrEP indication.

"The REMS for Truvada for the PrEP indication is aimed at educating health care professionals and uninfected individuals to help ensure its safe use for this indication without placing an unnecessary burden on health care professionals and patients," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

Truvada's safety and efficacy for PrEP were demonstrated in two large, randomized, double-blind, placebo-controlled clinical trials. The iPrEx trial evaluated Truvada in 2,499 HIV-negative men or transgender women who have sex with men and with evidence of high risk behavior for HIV infection, such as inconsistent or no condom use during sex with a partner of positive or unknown HIV status, a high number of sex partners, and exchange of sex for commodities.

Results showed Truvada was effective in reducing the risk of HIV infection by 42 percent compared with placebo in this population. Efficacy was strongly correlated with drug adherence in this trial.

The Partners PrEP trial was conducted in 4,758 heterosexual couples where one partner was HIV-infected and the other was not (serodiscordant couples). The trial evaluated the efficacy and safety of Truvada and tenofovir versus placebo in preventing HIV infection in the uninfected male or female partner. Results showed Truvada reduced the risk of becoming infected by 75 percent compared with placebo.

No new side effects were identified in the clinical trials evaluating Truvada for the PrEP indication. The most common side effects reported with Truvada included diarrhea, nausea, abdominal pain, headache, and weight loss. Serious adverse events in general, as well as those specifically related to kidney or bone toxicity, were uncommon.

As a condition of approval, Truvada's manufacturer, Gilead Sciences, Inc., is required to collect viral isolates from individuals who acquire HIV while taking Truvada and to evaluate these isolates for the presence of resistance. Additionally, the company is required to collect data on pregnancy outcomes for women who become pregnant while taking Truvada for PrEP and to conduct a trial to evaluate drug adherence and its relationship to adverse events, risk of seroconversion, and resistance development in seroconverters. Gilead has committed to provide national drug utilization data in order to better characterize individuals who utilize Truvada for a PrEP indication and to develop an adherence questionnaire that will assist prescribers in identifying individuals at risk for low compliance.
Gilead Sciences, Inc. is based in Foster City, Calif.