FDA Approves Truvada as PrEP

July 16, 2012 By Tim Horn

The U.S. Food and Drug Administration (FDA) has approved Truvada (tenofovir plus emtricitabine) as the first prescription drug—to be used daily and in conjunction with condoms and other safer-sex measures—to prevent HIV among those at high risk for the infection. Truvada's approval as pre-exposure prophylaxis (PrEP) was announced via statements from both the FDA and Truvada's manufacturer, Gilead Sciences.

"As part of PrEP, HIV-uninfected individuals who are at high risk will need to take Truvada daily to lower their chances of becoming infected with HIV should they be exposed to the virus," the FDA said. "Truvada for PrEP is meant to be used as part of a comprehensive HIV prevention plan that includes risk reduction counseling, consistent and correct condom use, regular HIV testing, and screening for and treatment of other sexually transmitted infections. Truvada is not a substitute for safer-sex practices."

The approval follows the May 10 recommendation by the FDA's Antiviral Drugs Advisory Committee to approve the drug as pre-exposure prophylaxis (PrEP) in various high-risk populations: men who have sex with men, HIV-negative partners in serodiscordant relationships and other individuals at risk for acquiring HIV through sexual activity.

"The only way we are going to end the epidemic is through a combination approach," said Susan Buchbinder, MD, of the San Francisco Department of Health, at the May advisory committee meeting. Noting that condoms are not 100 percent effective—in part because of improper use and breakage—and that behavioral intervention strategies aren't universally successful, she explained that what's needed "are new treatments and prevention strategies to have a major impact on the US epidemic."

"This is an enormous turning point, a real game changer, in the fight against HIV," said Jim Pickett, AIDS Foundation of Chicago's director of prevention advocacy and gay men's health. "The toolbox we have been working for decades to expand now has Truvada as PrEP."

Numerous data sets from the clinical trials were reviewed by the FDA, including results from the National Institutes of Health (NIH)-funded international iPrEx study and the University of Washington's Partners PrEP study conducted in Kenya and Uganda. These studies found that Truvada reduced the risk of acquiring HIV infection by 42 and 75 percent, respectively, with even higher rates of effectiveness among trial volunteers who strictly adhered to their daily regimen.

Safety First

As a part of its approval, the FDA is strengthening the warning section of Truvada's package insert to alert health care providers and at-risk individuals that Truvada for PrEP must only be used by those who are confirmed to be HIV negative prior to prescribing the drug. The FDA also notes that HIV testing should be conducted at least every three months while Truvada-as-PrEP is being used to reduce the risk of developing HIV resistant to tenofovir and/or emtricitabine.

The FDA has also required a Risk Evaluation and Mitigation Strategy (REMS). According to Gilead, this will include a Truvada medication guide with each Truvada PrEP prescription and training and education through a program for health care providers. Both initiatives will address not only HIV acquisition and the development of drug resistance, but will also underscore another serious risk: The need for careful prescribing, adherence and follow-up practices for individuals with chronic hepatitis B virus (HBV) infection, who can experience acute liver disease exacerbations if tenofovir and emtricitabine (both are effective against HBV) are not taken correctly or are stopped abruptly.

Gilead is also required to collect blood samples from individuals who acquire HIV while taking Truvada so that their HIV can be tested for resistance to tenofovir and/or emtricitabine. 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 levels of drug adherence and their relationship to adverse events, risk of seroconversion, and resistance development in those who do become infected with the virus while using the drug.

Gilead has committed to provide national drug utilization data in order to better characterize individuals who utilize Truvada as PrEP and to develop a PrEP registry project to assess adherence over time.

During the advisory committee hearing, Gilead also committed to providing vouchers for free HIV testing, HBV testing and condoms. The company will also provide assistance for drug-resistance testing for individuals who become infected with HIV while using Truvada and an opt-in testing reminder service.

Based on the iPrEx results, in January 2011 the Centers for Disease Control and Prevention (CDC) issued interim guidance on Truvada as PrEP among high-risk adult MSM. CDC is currently developing formal U.S. Public Health Service guidelines for the use of PrEP among both men and women, which will address procedures for HIV testing and health screening prior to PrEP initiation, as well as ongoing monitoring for cases of HIV infection that may occur despite PrEP use, possible drug resistance among those who become infected, side effects and clinical toxicities.

Looking Forward

Many HIV oranizations are embracing the approval of Truvada as PrEP, while also stressing the need for careful access planning in the real world.

"Access is paramount," said the HIV prevention advocacy group AVAC in a statement. "We will monitor and advocate that FDA approval is followed by implementation that ensures daily oral

PrEP using [Truvada] is affordable through government assistance programs, Gilead's patient assistance program and through private health insurance. State of the art HIV prevention is a right and a public health imperative, not a privilege. It is important that we explore all avenues for access and affordability of [Truvada] as PrEP."

Judith Aberg, MD, of the HIV Medicine Association agrees, stressing that implementation of PrEP must not contribute to HIV-related healh care disparities. "This is a particular concern because the low income and minority populations most heavily affected by HIV infection are less likely to be engaged in health care and are more likely to be uninsured or rely on Medicaid coverage," she said.

To reduce disparties, Aberg raises a number of key issues. For starters, she says, "funding for safety-net programs serving people with HIV, such as the Ryan White program, should not be diverted to support PrEP." She adds that "further studies of PrEP among women, especially women of color, should be conducted" and, importantly, that "the U.S. Prevention Services Trask Force should be encouraged to review coverage for PrEP...to faciliate coverage by insurers, including Medicaid programs."

"It's going to take time for health care systems around the country to figure out how to offer PrEP," Dan Van Gorder of the San Francisco-based advocacy group Project Inform explains. "But that doesn't mean that people who perceive themselves to be at high risk for HIV shouldn't have conversations with their doctors about it now."

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