

PRESS STATEMENT

UNAIDS welcomes approval by the US to use antiretroviral drug combination to prevent sexual transmission of HIV

FDA gives approval for the use of antiretroviral therapy to prevent HIV in people who do not have the virus in the United States

GENEVA, 16 July 2012—The Joint United Nations Programme on HIV/AIDS (UNAIDS) welcomes today's announcement by the United States' Food and Drug Administration (FDA) for the use of an antiretroviral drug combination (emtricitabine/tenofovir disoproxil fumarate) to prevent the sexual transmission of HIV for people who do not have HIV, but who are at high risk of being exposed to the virus.

HIV prevention of this kind is called pre-exposure prophylaxis—commonly known as PrEP. Emtricitabine and tenofovir disoproxil fumarate have been used to treat HIV infection since 2004, in combination with other antiretroviral drugs. This is the first time that an antiretroviral pill has been approved for use by people who do not have HIV.

The FDA has approved the drug combination for use as part of a comprehensive HIV prevention strategy that includes condom use and other safer sex practices, risk reduction counselling and control of other sexually transmitted infections. Regular HIV testing and counselling is an essential part of approved use for prevention, since there is a danger of drug resistance if used by people who have HIV but do not know they are living with the virus.

The decision of the US FDA is based on their review of results from recent clinical trials which have found that a daily oral dose of tenofovir, or of the combination emtricitabine/tenofovir disoproxil fumarate, when taken as prescribed by people who do not have the virus, provided significant prevention benefit.

The iPrEx study among men who have sex with men found that PrEP using the emtricitabine/tenofovir disoproxil fumarate combination decreased HIV transmission by 42% on average, and up to 73% among men who took the pill regularly. The Partners PrEP study found 75% protection among serodiscordant couples in studies in Kenya and Uganda, and the TDF2 trial in Botswana found PrEP to be roughly 63% effective among serodiscordant couples. In all three studies, oral PrEP was provided as part of a comprehensive prevention package of services, and in all three studies showed that adherence to the prescribed regimen was critical to its effectiveness.

The results from the studies showed the potential effects of combination prevention approaches—combining consistent condom use, frequent HIV testing, counselling, and treatment of sexually transmitted infections with pre-exposure prophylaxis for maximum prevention gains.

UNAIDS underlines that no single intervention is completely protective in preventing HIV transmission, which is why UNAIDS advocates strongly for combination prevention, including condom use for individuals at high risk of HIV infection.

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UNAIDS

The Joint United Nations Programme on HIV/AIDS (UNAIDS) leads and inspires the world to achieve its shared vision of zero new HIV infections, zero discrimination and zero AIDS-related deaths. UNAIDS unites the efforts of 11 UN organizations—UNHCR, UNICEF, WFP, UNDP, UNFPA, UNODC, UN Women, ILO, UNESCO, WHO and the World Bank—and works closely with global and national partners to maximize results for the AIDS response. Learn more at unaids.org and connect with us on Facebook and Twitter.