

# Pre-Exposure Prophylaxis (PrEP) for HIV Prevention



## Key points:

- In July 2012, Gilead's Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) became the first antiretroviral product to be approved in the United States for use in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in uninfected adults at high risk – a strategy called pre-exposure prophylaxis (PrEP).
- Truvada for a PrEP indication is not intended to replace other prevention tools such as condoms, but when taken as directed and used in combination with other prevention strategies, Truvada for a PrEP indication has demonstrated the potential to help reduce new HIV infections.
- The U.S. Centers for Disease Control and Prevention (CDC) recommends Truvada for a PrEP indication for individuals at substantial risk for contracting HIV.
- The World Health Organization (WHO) “strongly recommends” that men who have sex with men (MSM) consider taking PrEP as an additional prevention strategy.
- Gilead is helping to ensure that Truvada for a PrEP indication is implemented safely and effectively.

Globally, more than two million adults became infected with HIV in 2014, and in the United States the number of new infections – some 50,000 annually – has not declined significantly in more than a decade.<sup>1</sup> Pre-exposure prophylaxis (PrEP) is the use of antiretroviral medication by HIV-negative individuals to stay uninfected. It is a prevention strategy that has been shown to be effective in clinical trials in reducing the risk of contracting HIV when it is adhered to correctly.

## Research in Support of PrEP

Gilead is committed to developing strategies that prevent the transmission of HIV and continues to support ongoing research and demonstration projects to evaluate the effectiveness of Truvada for a PrEP indication in real-world settings. Support for the U.S. Food and Drug Administration's approval of Truvada for a PrEP indication came from two large-scale clinical trials:<sup>2</sup> iPrEx, conducted by the U.S. National Institutes of Health among men who have sex with men, and Partners PrEP, conducted by the University of Washington among heterosexual couples. Both studies found that for HIV-negative individuals taking Truvada the risk of HIV infection was reduced. Gilead donated study drug for PrEP clinical trials and assisted the researchers with medical and clinical information about Truvada.

## Public Health Guidance on Implementation

WHO, CDC and the U.S. Panel of the International Antiviral (formerly AIDS) Society (IAS) have all issued public health guidance on PrEP.

CDC's final guidance, released in May 2014, recommends PrEP for individuals at substantial risk for contracting HIV.<sup>3</sup> The guidance advises physicians and healthcare providers on how to assess and identify individuals who may be appropriate candidates for PrEP, based on their reported risk behaviors. It also provides guidance on how to support adherence to PrEP among individuals taking Truvada, because it is essential that people take the medication on a daily basis if it is to be effective as an HIV prevention tool. CDC also stresses that PrEP is not for everyone – it should be targeted to individuals at substantial risk for HIV infection and carefully monitored by a physician. It is critical that people using PrEP be confirmed to be HIV-negative prior to use and on an ongoing basis.

In July 2014, WHO released consolidated prevention guidelines for key populations at greatest risk for HIV infection, including MSM. In the updated guidelines, WHO for the first time “strongly recommends” that MSM consider taking PrEP as an additional method of preventing HIV, along with the use of condoms. WHO estimates that PrEP could achieve a 20- to 25-percent reduction in new HIV infections among MSM globally over 10 years, averting one million new infections.<sup>4</sup>

Also in July 2014, the U.S. Panel of the IAS published clinical practice guidelines for HIV prevention, recommending that PrEP be prioritized for individuals at high risk of HIV infection, particularly those recently diagnosed with a sexually transmitted infection and those who inject drugs or share needles.<sup>5</sup>

## Gilead's Role

Gilead believes that Truvada for a PrEP indication is an important HIV prevention tool. We are working with the healthcare community to ensure that patients and providers have accurate information about the appropriate use of Truvada for a PrEP indication. We also provide grants to community organizations that are raising awareness about PrEP among at-risk populations through education and training, and we support demonstration projects and research efforts that are seeking to identify optimal implementation strategies for PrEP as a new HIV prevention tool.

Additionally, Gilead believes that its medicines should be accessible to individuals who could benefit from them, regardless of their ability to pay for healthcare. Gilead's Truvada for PrEP Medication Assistance Program helps eligible HIV-negative adults in the United States who do not have insurance obtain access to Truvada for PrEP. For eligible individuals who have insurance, Gilead offers a co-pay assistance program to help offset out-of-pocket costs. Gilead recently enhanced these programs to ensure that the assistance provided for Truvada is consistent, regardless of whether an individual needs access for prevention or treatment.

## Additional Regulatory Approvals

Regulatory applications for Truvada for PrEP were filed in South Africa in 2013, in Thailand and Brazil in 2014 and in Australia and Canada in 2015. At the request of the French National Agency for Medicines and Health Products Safety (ANSM), Gilead also has provided data to permit an assessment of Truvada for a PrEP indication, which could result in a recommendation for temporary use in France.

### References

- <sup>1</sup> UNAIDS. The Gap Report (2014). Available online [here](#).
- <sup>2</sup> Grant R et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *New England Journal of Medicine*, 2010; Baeten et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *New England Journal of Medicine*, 2012.
- <sup>3</sup> US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014. A clinical practice guideline. May 2014. Available online [here](#).
- <sup>4</sup> World Health Organization. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. July 2014. Available online [here](#).
- <sup>5</sup> Marrazzo JM et al. HIV prevention in clinical care settings: 2014 recommendations of the International Antiviral Society–USA Panel. *JAMA*, 2014. Available online [here](#).