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**AVAC welcomes Gilead's submission of PrEP Data to FDA**

**Full review of all available data will help point the way forward for Truvada for PrEP use**

*New York, NY* – An important step to expanding effective HIV prevention strategies has been taken by Gilead Sciences, Inc., says AVAC. Today, Gilead Sciences announced that it has submitted a dossier of research data to the US Food and Drug Administration (FDA) related to the use of the antiretroviral treatment drug TDF/FTC (tenofovir/emtricitabine, brand name Truvada) as a pre-exposure prophylaxis (PrEP) HIV prevention strategy.

PrEP for HIV prevention refers to the use of antiretroviral medications by HIV-negative people to prevent HIV infection. TDF/FTC, or Truvada, is currently used as part of highly effective combination antiretroviral treatment for HIV-positive people. Gilead announced that it was seeking FDA approval for a label change indicating that Truvada can reduce the risk of HIV infection in HIV-negative adults.

“The FDA should place Truvada for PrEP on its accelerated, priority review track. A determination from this regulatory agency on new labeling and other conditions of use would catalyze and clarify decision-making in the US and potentially internationally about where and how to use TDF/FTC as an HIV prevention strategy,” said Mitchell Warren, AVAC executive director. “Approval is not guaranteed as a result of today’s filing. AVAC looks forward to participating in the process that will allow responsible input to any review that promotes safe use to those who may potentially benefit from PrEP. It will also be critical to insure continued and unfettered access to TDF/FTC for HIV-positive people as part of life-saving treatment.”

Every year more than 50,000 people are newly infected with HIV in the United States and rates of infection have remained steady for many years, underscoring the need for new HIV prevention options for gay men and others at high risk of HIV infection in the US. Globally, rates of HIV infection have declined but remain unacceptably high, with women at particularly high risk. More than 2.7 million people were infected with HIV in 2010.

Two major international efficacy trials have found that TDF/FTC is safe and reduces risk of HIV infection among HIV-negative people. The iPrEx study among gay and bisexual men and transgender women, and the Partners PrEP study among stable heterosexual couples in which one partner is HIV-positive and one HIV-negative. In addition, TDF2, a smaller trial, provided additional information about the drug in young heterosexual men and women.

The FEM-PrEP trial among heterosexual African women at high risk of HIV infection recently determined that participants counseled to use oral daily TDF/FTC did not have any reduction in HIV risk compared to those participants counseled to use daily placebo. Additional data from this trial are expected in early 2012. The multi-arm VOICE trial, which is also looking at oral

TDF/FTC among African women, is scheduled to report results in 2013. The VOICE trial recently announced that the trial arms testing oral TDF alone and 1% tenofovir gel did not provide any protection. (All participants in all PrEP trials were counseled about and provided with a comprehensive package of proven prevention tools.)

“Even though there have been mixed results on PrEP using TDF/FTC from various clinical trials, both the iPrEx and Partners PrEP data are strong and suggest that, in some contexts, a daily oral pill is a powerful prevention tool that individuals can use to reduce their HIV risk,” Warren said. “More analysis of the full range of trials will tell us why this strategy works in some populations, and not in others, but the need for new options in key groups—including gay men and women in stable partnerships—is so great that proceeding with the FDA review process is an appropriate and important next step.”

Participants in both the iPrEx and Partners trials are continuing to receive TDF/FTC in “open-label” periods of those trials, in which all participants are offered the drug that has been shown to be effective in reducing HIV risk. These open-label studies will generate information on patterns of adherence, impact on HIV risk and other variables outside of a highly controlled clinical trial environment. Visit [www.avac.org/prep](http://www.avac.org/prep) for more information about ongoing and completed PrEP studies.

“We know that PrEP is not a magic bullet and will not be the right intervention for everyone at risk of HIV infection, but it could be an important prevention option for many people who are unable to use other proven prevention options. An FDA-approved label indication and reasonable conditions of use would make it easier for providers and their clients to consider PrEP as a safe and effective prevention option, and pave the way for appropriate access in the United States,” Warren said. “We also know that TDF/FTC is an important part of treatment regimens for people living with HIV worldwide, and that decisions about when and how to use PrEP based on TDF/FTC can only happen in the context of uncompromised treatment access for people living with HIV.”

“We look forward to the rigorous FDA review process, which will include opportunities for public comment and debate about how Truvada as PrEP might be used,” Warren said. “At the same time, we must continue to rapidly expand testing, treatment and voluntary medical male circumcision, amongst the array of evidence-based interventions, while also accelerating research and development of additional new options, notably a range of ARV- and non-ARV-based prevention methods and vaccines to protect against HIV,” Warren added.

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*About AVAC:* Founded in 1995, AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of AIDS vaccines, male circumcision, microbicides, PrEP and other emerging HIV prevention options as part of a comprehensive response to the pandemic. More is available at [www.avac.org](http://www.avac.org).