**iPrEx Fact Sheet: Rollover Study and Next Steps**

**Key Facts**

- iPrEx study results are a clear and important step forward in HIV prevention research. PrEP with FTC/TDF has the potential to be a highly effective HIV prevention method when combined with standard prevention tools.

- A number of other PrEP studies are currently underway in different communities at risk and should continue. Results of the iPrEx study cannot be extrapolated beyond the study population of MSM.

- Whether iPrEx study data alone are sufficient to warrant approval of FTC/TDF as PrEP is a decision that must be made by national and international regulatory authorities after careful review and discussion with experts and people impacted by the epidemic.

- Additional data from the iPrEx study will be collected, analyzed and released in the coming months. These will provide approximately three additional months of PrEP efficacy data.

- Results of sub-studies currently underway will also provide additional information on the effect of PrEP on bone mineral density, and on which groups were most able to take PrEP and achieve protective levels of medications. These data will provide important additional information and details, but are not expected to change the key findings from this study.

- An open label extension of the iPrEx study will provide all HIV-negative iPrEx participants who wish to enroll in this phase with access to FTC/TDF for HIV prevention for 18 months.

- The iPrEx rollover study will differ from the first iPrEx study in two ways: all participants who choose to participate will receive and will know they are receiving FTC/TDF PrEP; and all participants will have the information about efficacy and safety of PrEP learned in the first iPrEx study.

- The iPrEx rollover study will provide additional information to help determine whether adherence and drug exposure increases, or if risk behavior changes, when trial participants receive the information that the original iPrEx study has provided regarding the safety and efficacy of PrEP.

- The iPrEx rollover study will also provide additional opportunities to detect any rare safety events; collect additional safety data regarding long-term PrEP use; estimate the seroconversion rate when trial participants are provided with information regarding the safety and efficacy of PrEP; and determine the effects of PrEP on the course of clinical HIV infection, including drug resistance, plasma HIV RNA levels and CD4+ T cell counts.

- Importantly, the iPrEx rollover will provide trial participants with an intervention that has been proven to decrease the risk of HIV acquisition in MSM when combined with standard prevention tools.
iPrEx study results are a clear and important step forward in HIV prevention research. PrEP with FTC/TDF has the potential to be a highly effective HIV prevention method when combined with standard prevention tools.

A number of other PrEP studies are currently underway in different communities at risk and should continue. iPrEx results cannot be extrapolated beyond MSM, and the iPrEx study alone does not offer enough information to eliminate the need for further study.

Whether iPrEx study data alone are sufficient to warrant approval of FTC/TDF as PrEP is a decision that must be made by national and international regulatory authorities after careful review of the data and discussion with communities of experts and people impacted by the epidemic. The iPrEx investigators urge WHO, UNAIDS, other global HIV policymaking bodies and national regulatory authorities, especially in the countries in which iPrEx took place, to meet promptly to review these data and to develop clear recommendations for next steps in the study of PrEP.

The iPrEx study raises important issues that require further research. One such issue is the need to understand and develop strategies to support pill-taking behavior and improved use of the therapy in order to further reduce an individual’s risk of becoming infected with HIV.

Other PrEP trials currently underway will provide important information about PrEP efficacy following penile, vaginal or needle exposure. Two of these trials also compare TDF with FTC/TDF. These alternative regimens may differ in efficacy, drug resistance risk, costs and tolerance. A large proportion of participants in a PrEP study among injection drug users in Thailand, sponsored by the CDC, receive directly observed therapy, which will provide information on the efficacy of PrEP delivered in the clinic.

**iPrEx rollover study**

An open label extension, or “rollover” of the iPrEx study will provide all HIV-negative iPrEx participants who wish to enroll in this phase with access to FTC/TDF for HIV prevention for 72 weeks. The rollover study should provide additional information about how to improve pill-taking, and whether people are more likely to take the pill now that it has been shown partial efficacy in preventing HIV infection.

The iPrEx rollover study will differ from the first iPrEx study in two ways: all participants who choose to participate will receive and will know they are receiving FTC/TDF PrEP; and all participants will have the information about the efficacy and safety of PrEP learned in the first iPrEx study.

- The open label iPrEx extension study will be conducted at all 11 iPrEx sites, beginning in early 2011. The study will report its findings in early 2013.
- All participants in the rollover study will receive a comprehensive package of HIV prevention interventions that include HIV risk reduction counseling, condoms and STI management.
The objectives of the rollover study are to:

- Determine if adherence and drug exposure increases when trial participants are provided with information regarding the safety and efficacy of PrEP.

- Determine if risk behavior changes when trial participants are provided with information regarding the safety and efficacy of PrEP.

- Increase the study power (the number of people participating and thus receiving the active PrEP drug) to detect rare safety events in HIV-uninfected persons receiving antiretroviral agents.

- Provide additional safety data regarding long-term PrEP use.

- Estimate the seroconversion rate when trial participants are provided with information regarding the safety and efficacy of PrEP.

- Determine the effects of PrEP on the course of clinical HIV infection, including drug resistance, plasma HIV RNA levels and CD4+ T cell counts.

- Provide trial participants with increased post-trial access to effective HIV prevention interventions, during the development of more sustainable PrEP programs and second generation studies.

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