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FOR IMMEDIATE RELEASE

Microbicide Trials Network Statement on the status of VOICE Study following announcement to close the FEM-PrEP trial

PITTSBURGH, April 18, 2011 – Today, researchers conducting an HIV prevention trial called FEM-PrEP announced that this study would be closing earlier than planned. FEM-PrEP has been testing whether daily use of an antiretroviral (ARV) drug called Truvada could prevent HIV infection in high-risk women in Kenya, Tanzania and South Africa, but an interim review of the study's progress by an Independent Data and Monitoring Committee (IDMC) determined that even if the study were to continue, it would not be able to conclude whether or not Truvada is effective.

FEM-PrEP researchers will be working to complete follow-up and data collection over the next three months. After this time, the team will conduct a full analysis of all available information. Until this final report is available, few conclusions can be drawn about FEM-PrEP, including the reasons why it is unable to answer the research questions it was designed to answer. The study was designed and implemented by FHI in partnership with African research centers.

While it is disappointing that FEM-PrEP will not be able to provide information about Truvada for preventing HIV in women, the decision to stop the study should have no immediate impact on the VOICE study. VOICE – Vaginal and Oral Interventions to Control the Epidemic – is an ongoing trial involving women in Uganda, South Africa and Zimbabwe testing Truvada as well as the ARV tablet tenofovir and a vaginal microbicide containing tenofovir in gel form. VOICE will help determine which approach – daily use of the gel or tablet – is safe, effective and preferred by women for preventing HIV.

VOICE is continuing to enroll participants and to follow women already in the study. VOICE began in September 2009 and will involve approximately 5,000 women. More than 4,200 women have been enrolled to date. Researchers expect to report results in early 2013.

Leading the VOICE study are Zvavahera Mike Chirenje, M.D., of the University of Zimbabwe in Harare, and Jeanne Marrazzo, M.D., M.P.H., from the University of Washington in Seattle, U.S.

VOICE is the flagship study of the Microbicide Trials Network (MTN), an HIV/AIDS clinical trials network funded by the National Institute of Allergy and Infectious Diseases with co-funding from the *Eunice Kennedy Shriver* Institute for Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. MTN principal investigator is Sharon Hillier, Ph.D., and co-principal investigator is Ian McGowan, M.D., Ph.D.

Another ongoing trial evaluating Truvada, as well as oral tenofovir, is the Partners PrEP study. Partners PrEP involves both men and women in serodiscordant relationships, in which one partner is HIV-infected and the other is not, in Kenya and Uganda. Partners PrEP has reached its target enrollment of 4,700 couples and expects to report study results in early 2013. The study is funded by the Bill & Melinda Gates Foundation.

FEM-PrEP began in July 2009 and had intended to enroll approximately 3,900 women, with results available in

2013. At the time of the "data lock" for the interim review by the IDMC, the study had enrolled 1,951 women. FEM-PrEP was funded by the U.S. Agency for International Development (USAID). Early support was also provided by the Bill & Melinda Gates Foundation.

An IDMC, also called a Data and Safety Monitoring Board (DSMB), is an independent group of clinical research experts, statisticians, ethicists and community representatives that provides additional oversight of a clinical study. An IDMC or a DSMB regularly reviews data while a clinical trial is in progress to ensure that participants are not being adversely affected by the study or study products. If the IDMC or DSMB has any safety concerns, it may, at any time, recommend that the study modify its procedures or be discontinued. In addition, the IDMC or DSMB may recommend halting the trial if there is compelling evidence for a product's effectiveness or if it becomes clear that the trial cannot answer whether a product is effective, a concept called futility. These committees look at analyses that are not available to the investigators or anyone else.

Women make up half of the more than 33 million people living with HIV/AIDS worldwide. In sub-Saharan Africa, six out of 10 new HIV infections in adults occur in women. In several southern African countries, young women aged 15 to 24 are at least three times more likely than their male peers to be infected with HIV. Among women, unprotected sex with an infected male partner remains the primary risk factor for HIV infection, and in many parts of the world, heterosexual intercourse is the driving force of the epidemic. Women are twice as likely as their male partners to acquire HIV during sex. Although correct and consistent use of male condoms has been shown to prevent HIV infection, often women are not able to choose if they are used.

Oral tenofovir (tenofovir disoproxil fumarate), known by the brand name Viread®, and Truvada, a combination tablet that contains tenofovir and emtricitabine, are both approved for the treatment of HIV when used in combination with other ARVs. Viread and Truvada are registered trademarks of Gilead Sciences, Inc., of Foster City, Calif., U.S. Both are being evaluated in clinical trials to determine if they also can prevent HIV in people who are HIV-negative, an approach known as oral pre-exposure prophylaxis, or PrEP. A recent trial called iPrEx found that daily use of Truvada was safe and reduced the risk of HIV by 42 percent among men who have sex with men.

Tenofovir gel is a vaginal microbicide that contains the same active ingredient as the oral tablet formulation of tenofovir. Microbicides are products designed to prevent or reduce the sexual transmission of HIV when applied topically on the inside of the vagina or rectum. In CAPRISA 004, there were 39 percent fewer infections among women who used tenofovir gel before and after sex compared to women who used a placebo gel. In VOICE, women are using gel daily, regardless of when they have sex. The U.S. Food and Drug Administration (FDA) has indicated that it will consider approving tenofovir gel as an HIV prevention method for women depending on the results of VOICE. The FDA has also granted the gel Fast Track designation, which allows for its expedited review.

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More information about VOICE can be found at www.mtnstopshiv.org/news/studies/mtn003 . Information about the closure of FEM-PrEP can be found at www.fhi.org.

About the MTN

The Microbicide Trials Network (MTN) is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). The MTN brings together international investigators and community and industry partners who are devoted to reducing the sexual transmission of HIV through the development and evaluation of products applied topically or administered orally, working within a unique infrastructure specifically designed to facilitate the research required to support licensure of these products for widespread use.

Based at the University of Pittsburgh and Magee-Womens Research Institute in Pittsburgh, Pennsylvania, USA, MTN's core operations are supported by a network laboratory at the University of Pittsburgh, a statistical and data management center housed within the Statistical Center for HIV/AIDS Research & Prevention (SCHARP) at the Fred Hutchinson Cancer Research Center, and FHI, a global organization with expertise conducting clinical protocols. MTN conducts its trials at clinical research sites located in seven countries and spanning three continents. MTN receives its funding from three NIH institutes: NIAID, the National Institute of Mental Health and the Eunice Kennedy Shriver National Institute of Child Health and Human Development. Among the groups developing and evaluating microbicides for HIV prevention globally, the MTN is the only one funded by NIH.

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