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**FOR IMMEDIATE RELEASE**

## **HIV Prevention Trial Milestone: VOICE Study Completes Enrollment of 5,000 Women**

### **Pivotal trial of tenofovir gel and the ARVs tenofovir and Truvada on track for completion next year**

**PITTSBURGH, June 6, 2011** – The Microbicide Trials Network (MTN) announced today that it has completed enrollment into its flagship study, VOICE – Vaginal and Oral Interventions to Control the Epidemic. VOICE is a major HIV prevention trial testing whether antiretroviral (ARV) drugs commonly used in the treatment of HIV are safe and effective for preventing sexual transmission of HIV in women as either a tablet or a vaginal microbicide gel. As of today, 5,000 women were enrolled in the study at 15 clinical research sites in Uganda, South Africa and Zimbabwe.

VOICE is a Phase IIb trial designed to evaluate daily use of the ARV tablets tenofovir or Truvada® and a vaginal microbicide containing tenofovir in gel form. As the first effectiveness study of a microbicide gel that women use every day, and the only trial evaluating both a tablet and a gel in the same study, VOICE will help determine which approach is safe, effective and preferred by women for preventing HIV.

Women in the study were randomly assigned to one of five groups to determine the product they would use daily during the trial – either tenofovir, Truvada or a placebo tablet; or tenofovir gel or a placebo gel. There are approximately 1,000 women in each group. As part of the study, all participants receive ongoing comprehensive HIV prevention services, including counseling, condoms and diagnosis and treatment of STIs.

The study began in September 2009 and is on target to complete follow-up in June of 2012. By that time, all women will have used their study product for at least one year, some for nearly three years. Women will then be followed for an additional two months. Results are anticipated to be available early 2013.

VOICE has taken on added importance in the last year – in the wake of two trials that reported promising results, one involving tenofovir gel and the other oral Truvada, and of a third study testing oral Truvada that has announced its premature closure. .

The CAPRISA 004 study of tenofovir gel, reported in July 2010, found that the risk of acquiring HIV was reduced by 39 percent among women who used tenofovir gel before and after sex compared to women who used a placebo gel. Soon after, the U.S. Food and Drug Administration (FDA) indicated that it would consider approving tenofovir gel as an HIV prevention method for women based primarily on the results of CAPRISA 004 and VOICE. The FDA also granted the gel Fast Track designation, which allows for expedited review. Depending on the final outcome of VOICE, tenofovir gel feasibly could be the first HIV prevention product ever to be approved for women.

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The results of the iPrEx Study demonstrated for the first time that daily use of an ARV tablet can help prevent HIV. Truvada was safe and reduced the risk of HIV by 44 percent among men who have sex with men, iPrEx researchers reported in November 2010. Whether Truvada is effective in other high-risk populations, such as women in sub-Saharan Africa, is a question that VOICE and another study called Partners PrEP will try to answer. Partners PrEP, which involves serodiscordant couples in which one partner is HIV positive and the other is HIV negative, is evaluating both Truvada and tenofovir (as is VOICE) and expects to be reporting results about the same time as VOICE. Meanwhile, a third trial, the FEM-PrEP Study, is preparing to close earlier than originally planned, the study team announced in early April. That's because an interim review by FEM-PrEP's independent data monitoring committee established that even if the study were to continue, it would not be able to conclude whether or not Truvada is effective for prevention of HIV in its study population of high-risk women.

Globally, women account for nearly half of the more than 33 million people living with HIV/AIDS. 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.

VOICE is a study of the MTN, an HIV/AIDS clinical trials network funded by the National Institute for 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 co-principal investigators are Sharon Hillier, Ph.D., and Ian McGowan, M.D., Ph.D., both of the University of Pittsburgh. VOICE is led by protocol co-chairs 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.

Oral tenofovir (tenofovir disoproxil fumarate), known by the brand name Viread<sup>®</sup>, 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. 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 inside the vagina or rectum. Gilead assigned a royalty-free license for tenofovir gel to CONRAD of Arlington, Virginia, and the International Partnership for Microbicides of Silver Spring, Maryland, in 2006.

Gilead and CONRAD are donating the study products for VOICE.

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More information about VOICE can be found at [www.mtnstopshiv.org/news/studies/mtn003](http://www.mtnstopshiv.org/news/studies/mtn003).

*About the Microbicide Trials Network*

The [Microbicide Trials Network](#) (MTN) is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. Based at Magee-Womens Research Institute and the University of Pittsburgh, the MTN brings together international investigators and community and industry partners who are devoted to preventing or reducing the sexual transmission of HIV through the development and evaluation of products applied topically to mucosal surfaces or administered orally.