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**FOR IMMEDIATE RELEASE**

**VOICE Study, a major HIV prevention trial for women, is launched in Zimbabwe**  
***Testing ARVs as prevention instead of treatment***

**PITTSBURGH, SEPT. 16, 2009** – Hopeful that some of the same antiretroviral (ARV) drugs used to treat HIV infection can also prevent it, researchers from the Microbicide Trials Network have enrolled the first participants into a new, large-scale clinical trial testing two approaches of the strategy in women.

The VOICE Study – Vagina and Oral Interventions to Control the Epidemic – will help determine whether applying a vaginal microbicide gel containing an ARV every day or taking an oral ARV tablet once a day can reduce a woman’s risk of acquiring HIV.

While the study’s primary aim is to evaluate the safety and effectiveness of the two regimens, an important question VOICE will also address is which of the two – the tablet or the gel – women will actually be more inclined to use. It is the first HIV prevention trial testing these two different approaches in the same study and the first effectiveness trial of a microbicide in which women use the gel every day instead of only at the time of sex.

Up to 5,000 women will be enrolled in VOICE at clinical trial sites in Uganda, South Africa, Zambia and Zimbabwe. Pending government approval, the study may also be conducted in Malawi. The Spilhaus Clinical Research Site at the University of Zimbabwe-University of California-San Francisco (UZ-UCSF) Clinical Trials Unit in Harare, began enrolling trial participants this week.

VOICE is being conducted under the leadership of the U.S. National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN), which is based at the University of Pittsburgh and Magee-Womens Research Institute.

“The HIV prevention field has not been without its share of disappointments. So, naturally we are excited that in VOICE we have not just one, but two promising approaches to evaluate. Hopefully, we’ll find that ARVs, which helped turn the tide in the treatment of HIV, can be a prevention powerhouse, too,” said Mike Chirenje, M.D., FRCOG, associate professor and consultant gynecologist in the department of obstetrics and gynecology at the University of Zimbabwe in Harare and co-chair of the VOICE Study.

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Women represent nearly 60 percent of adults living with HIV in sub-Saharan Africa, and in several southern African countries young women are at least three times more likely to be HIV-positive than young men. In most cases, women acquire HIV through sexual intercourse with an infected male partner.

Although correct and consistent use of male condoms has been shown to prevent HIV infection, women often cannot control if or when condoms are used by their male partners. Moreover, women are twice as likely as their male partners to acquire HIV during unprotected sex, due in part to biological factors that make them more susceptible to infection.

“Women need safe and effective methods for preventing HIV that they can control themselves. Importantly, women need methods that they are willing and able to use, because no approach can be truly effective if she leaves it in her purse or hidden in a drawer,” added Jeanne Marrazzo, M.D., M.P.H., associate professor of medicine in the division of allergy and infectious diseases at the University of Washington in Seattle, U.S.A., and VOICE Study co-chair with Dr. Chirenje.

Two ARV tablets are being tested in VOICE: tenofovir and Truvada<sup>®</sup>. Tenofovir, short for tenofovir disoproxil fumarate (TDF), is also known by the brand name Viread<sup>®</sup>, while Truvada is the brand name for a combination drug that contains tenofovir and another active ingredient called emtricitabine (FTC). Both are approved for treating HIV as part of antiretroviral therapy (ART). While at least three ARVs are typically used for ART, a single ARV tablet taken once a day is the regimen being tested for HIV prevention in current trials, including VOICE, an approach called pre-exposure prophylaxis (PrEP).

The vaginal microbicide being evaluated in VOICE, tenofovir topical gel, contains the activated form of the same ingredient in the tenofovir oral tablet. It is among a newer class of candidate microbicides – substances intended to reduce or prevent the sexual transmission of HIV and other sexually transmitted infections when applied topically inside the vagina or rectum – with specific activity against HIV.

Women in VOICE are randomly assigned to one of five study groups. Two groups will apply gel every day – either tenofovir gel or a placebo gel with no active ingredient. Three groups will be assigned to daily tablet regimens, taking either tenofovir, Truvada or a placebo tablet. Because the study is blinded, neither the participants nor the researchers will know who is in which gel or tablet group. Women will use the same product every day the entire time they are in the study, which is expected to be an average of 22.5 months.

All participants will receive regular HIV testing and risk-reduction counseling, condoms, and testing for sexually transmitted infections (STIs). Staff will refer any participant who acquires HIV or an STI during the study to appropriate treatment and care in her community.

Researchers at the Uganda and Zimbabwe sites are also conducting a companion study called VOICE B, or the Bone Mineral Density Sub-study. VOICE B will involve about 300 women who have been randomized to the oral tablet groups to determine the potential effects, if any, that the oral ARVs may have on bone health in HIV-negative women.

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Both studies were designed according to the most rigorous international medical practice and ethical standards and include numerous measures, beginning at the site level, intended to protect the safety and well-being of participants. All women participating in VOICE and VOICE B will provide written informed consent through a process that ensures they understand the procedures, as well as possible risks and benefits of the study. Safety will be monitored closely throughout their participation.

The VOICE Study is being funded by the National Institute of Allergy and Infectious Diseases (NIAID) 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.

Truvada and the oral and topical formulations of tenofovir were developed by Gilead Sciences, Inc., of Foster City, California, USA, which assigned a royalty-free license for the topical gel to the International Partnership for Microbicides of Silver Spring, Maryland., and CONRAD, of Arlington, Virginia., in December 2006. As co-sponsors of VOICE, Gilead is providing tenofovir and Truvada tablets free of charge, and CONRAD is providing both the gel and gel applicators at no cost.

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More information about the VOICE Study can be found at <http://www.mtnstopshiv.org/news/studies/mtn003>

*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 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.*