



## **HIV Prevention Research Remains Essential: The FACTS Consortium will continue studying tenofovir gel for HIV and HSV-2 prevention in women**

JOHANNESBURG, SOUTH AFRICA, 25 November 2011— The U.S. National Institute of Allergy and Infectious Diseases (NIAID) and the Microbicide Trials Network (MTN) announced today that the VOICE study, an HIV prevention study being conducted in several African countries, will stop evaluating the daily use of tenofovir gel for HIV prevention. The decision was made after an independent data and safety monitoring board (DSMB) determined that daily use of vaginal tenofovir gel was ineffective at preventing HIV infection in the women in the study.

“While it is disappointing that daily use of the gel was not effective, it is important to the microbicide field to know these results,” said Prof Helen Rees, Principal Investigator of the FACTS Consortium and Executive Director of the Wits Reproductive Health and HIV Institute. “It is encouraging that VOICE identified no safety concerns in daily use of tenofovir gel. FACTS 001 is more important than ever to determine if tenofovir gel used around the time of sex works to prevent HIV and HSV-2.”

The VOICE study and the FACTS 001 study have both been evaluating the safety and effectiveness of 1% tenofovir gel in preventing HIV infections in women. The FACTS 001 study is evaluating the effectiveness of tenofovir gel when used before and after sex, a regimen which was shown to reduce HIV infection by 39% and genital herpes by 51% among women in the CAPRISA 004 study. The VOICE study was evaluating the effectiveness of gel when used once daily.

It is not yet known why tenofovir gel did not work to prevent HIV in the women who participated in the VOICE study. Data from VOICE will only be available once the MTN completes the study in late 2012. VOICE – a study that had enrolled more than 5,000 women in South Africa, Zimbabwe and Uganda – was designed to evaluate two different strategies for preventing the sexual transmission of HIV in women: daily use of an investigational microbicide gel containing 1% tenofovir, an antiretroviral drug, and daily use of oral tablets including tenofovir alone or co-formulated with the drug emtricitabine (brand name Truvada). On 17 September, an earlier DSMB recommended stopping the oral tenofovir tablet arm as the study showed that oral tenofovir was not effective in the study participants in these countries. VOICE will continue to study the safety and effectiveness of oral Truvada for possible use to prevent HIV infection.

A separate study, the groundbreaking CAPRISA 004 study conducted in KwaZulu Natal, found in 2010 that tenofovir gel used before and after sex reduced women’s risk of HIV infection. The FACTS 001 study is being conducted to test the same strategy with the aim of confirming and expanding on the CAPRISA data.

“The Follow-on African Consortium for Tenofovir Studies (FACTS) team commends the MTN and VOICE teams for their ongoing contributions towards exploring new HIV prevention

interventions for women,” said Prof Glenda Gray, Protocol Co-chair of FACTS and Director of the Perinatal HIV Research Unit. “VOICE contributed important safety data toward the possible licensure of tenofovir gel. If FACTS 001 can confirm CAPRISA’s positive results, these combined effectiveness data, along with VOICE’s safety data on tenofovir gel, may enable the licensure of the first microbicide for women, and a powerful new tool for women to protect themselves from HIV and HSV-2.”

FACTS is a South African-led clinical research consortium established to conduct clinical studies to determine whether tenofovir vaginal gel – the same gel studied in VOICE and CAPRISA 004 – is safe and effective at protecting women from sexual transmission of HIV and genital herpes infection. The consortium is conducting FACTS 001, a Phase III placebo-controlled study designed to test the safety and effectiveness of 1% tenofovir gel used before and after sex to protect women against HIV and also against herpes simplex virus (HSV-2). The study began in October 2011, and will enrol a minimum of 2,200 women at nine clinical research sites around South Africa. The study is sponsored by CONRAD and funded by the South African Department of Science and Technology, the U.S. Agency for International Development (USAID), Bill & Melinda Gates Foundation and the South African Department of Health. CONRAD and Gilead Sciences, Inc. are providing the study products for free.

Multiple studies are essential to determine whether interventions and products being tested in various regimens are safe and effective, and have the potential to protect diverse populations most in need of new HIV interventions. We must continue to find ways to prevent infection to save lives now and so that future generations will be free of HIV and AIDS.

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#### **ABOUT FACTS**

FACTS is a South African-led research consortium established in 2010 to conduct clinical studies to determine whether tenofovir vaginal gel is safe and effective at protecting women from HIV and herpes simplex virus (HSV-2), the virus that causes genital herpes. The consortium is based at the Wits Reproductive Health and HIV Institute (WRHI) in Johannesburg, with data management coordinated by the Perinatal HIV Research Unit (PHRU). Other South African research organisations participating in the consortium include the Aurum Institute, the Desmond Tutu HIV Foundation, MatCH, the Medunsa Clinical Research Unit, the Qhakaza Mbokodo Research Clinic, and the Setshaba Research Centre.

The FACTS consortium is planning two studies. FACTS 001 is sponsored by CONRAD and funded by the South African Department of Science and Technology, the U.S. Agency for International Development (USAID), Bill & Melinda Gates Foundation and the South African Department of Health. CONRAD and Gilead Sciences, Inc. are providing the study products for free.

FACTS 002 is an adolescent safety study being developed to test the safety and acceptability of tenofovir gel in 16 and 17-year-old South African young women.

If the FACTS studies find positive results, these combined data could help enable licensure of the first microbicide product and subsequently provide women with an important new women-controlled HIV prevention method.

For more information on FACTS and the FACTS studies, please visit our website at: [www.facts-consortium.co.za](http://www.facts-consortium.co.za)

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