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FOR IMMEDIATE RELEASE

Results of CAPRISA 004 a turning point for HIV prevention, say MTN researchers conducting VOICE

Tenofovir gel used before and after sex reduced HIV by 39 percent, raises bar for VOICE Study testing *daily* gel use and ARVs for preventing HIV in women

VIENNA, July 19 – Researchers who conducted a study testing a vaginal microbicide with an antiretroviral (ARV) drug called tenofovir found its use before and after sex was significantly more protective against HIV infection than a placebo gel among women at high risk of HIV. Results of the study, known as CAPRISA 004, are to be reported at the International AIDS Conference (AIDS 2010) in Vienna and published online by the journal *Science*.

CAPRISA 004 involved 889 women from Durban and a nearby rural community in South Africa, where women are at especially high risk of acquiring HIV through sexual intercourse. Women were randomly assigned to one of two study groups – tenofovir gel or placebo gel with no active ingredient –and instructed to use the study product in a regimen timed before and after sex. At the end of the study, there were 39 percent fewer HIV infections among women who used tenofovir gel before and after sex than among those who used the placebo gel. The study was conducted by the Centre for the AIDS Programme of Research in South Africa (CAPRISA).

"This study has established proof of concept that a vaginal microbicide containing an ARV can protect women from HIV. This is an incredibly important achievement for which the CAPRISA team is to be congratulated. For all of us in the HIV prevention field, this result has shown that it may be possible to leverage this initial success using a single ARV at the time of sex into more potent approaches that could be 50, 60 or even 70 percent effective for prevention of HIV. The results of this study have reinvigorated the field," commented Sharon Hillier, Ph.D., professor and vice chair for faculty affairs, and director of reproductive infectious disease research in the department of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of Medicine, and principal investigator of the Microbicide Trials Network (MTN).

The MTN currently is conducting another study called VOICE – Vaginal and Oral Interventions to Control the Epidemic – that will provide evidence about the safety and efficacy of tenofovir gel used daily,

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regardless of when participants have sex. VOICE, sometimes referred to as MTN-003, also is evaluating another promising approach called oral pre-exposure prophylaxis (PrEP), which involves daily use of an ARV tablet (tenofovir or Truvada®). VOICE is the first HIV prevention trial testing 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 around the time of sex. The study plans to enroll about 5,000 women at sites in South Africa, Uganda, Zimbabwe and Malawi. Nearly 1,000 women have been enrolled so far.

Tenofovir gel and the tablets being tested in VOICE and other PrEP trials incorporate some of the same ARV medicines used successfully for treatment of HIV. The hope is that they will also be safe and effective for HIV prevention.

"CAPRISA's contribution to our understanding of how topically applied ARVs could prevent HIV is extraordinary. The results of this study bode well for the future of microbicide research and for investigation of ARV-based prevention for men and women worldwide. And as the first completed effectiveness study involving ARVs for prevention, CAPRISA 004 raises the bar for VOICE. I would argue that VOICE is more relevant than ever. We're now in a position where we may learn that daily use of tenofovir gel is equally safe and could possibly be even more effective than the regimen tested in CAPRISA 004," commented MTN Co-Principal Investigator Ian McGowan, M.D., Ph.D., FRCP, professor of medicine in the division of gastroenterology, hepatology and nutrition with a joint appointment in the department of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of Medicine.

"It is gratifying that we are a step closer to identifying a safe and effective HIV prevention method for women. But to know for certain that tenofovir gel is effective, additional studies must be performed, because we can't be sure that what worked for the women in CAPRISA 004 will be the same for women elsewhere," 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.

"VOICE hopes to answer some of the questions about tenofovir gel – and oral PrEP – that CAPRISA 004 was not designed to address."

"Both studies are about finding safe, effective choices for women, whether that choice is a gel used with sex or a gel or tablet used every day," added Jeanne Marrazzo, M.D., M.P.H., VOICE Study co-chair, and professor of medicine in the division of allergy and infectious diseases at the University of Washington in Seattle. "Some women may prefer to use a product only when they have sex; others may prefer – or require – protection more often. CAPRISA 004 and VOICE are complementary studies that together can give us a substantial amount of information about these approaches. That's important, because we have to be certain that the evidence base for any approach is rock solid before that intervention should be made available more broadly to women at risk for HIV."

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VOICE is funded by the by the Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases with co-funding from the National Institute of Mental Health and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, all components of the U.S. National Institutes of Health (NIH).

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.

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NOTE TO MEDIA ATTENDING AIDS 2010:

The following expert sources are available for in-person interviews and comment on the results of CAPRISA 004: Ian McGowan, M.D., Ph.D., Microbicide Trials Network (MTN) co-principal investigator; Mike Chirenje, M.D., VOICE Study co-chair; Patrick Ndase, M,D., MTN regional physician.

More information about CAPRISA 004 can be found at www.caprisa.org. 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 (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 Family Health International, 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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