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Researchers Reformulate Tenofovir Vaginal Gel for Rectal Use

'New' gel safe and effective in laboratory studies

BOSTON, Feb. 28, 2011 – A change in the formulation of tenofovir gel, an anti-HIV gel developed for vaginal use, may make it safer to use in the rectum, suggests research presented today at the 18th Conference on Retroviruses and Opportunistic Infections (CROI). In laboratory tests of rectal tissue, researchers from the Microbicide Trials Network (MTN) found the reformulated gel was less harmful to the lining of the rectum than the original vaginal formulation, and just as effective in protecting cells against HIV.

Researchers are now testing the reformulated gel in an early-phase clinical trial with men and women. Results from these and future studies will have important implications for the development of a rectal microbicide that could help protect against HIV or other sexually transmitted infections during anal sex.

Tenofovir gel has shown significant promise in reducing HIV risk in women through vaginal sex. But because the rectal epithelium – the lining of the rectum that serves as the first line of defense against HIV – is much thinner than the vaginal lining, the gel may not be safe or effective to use rectally. By its nature, tenofovir gel is hyperosmolar – contains a higher concentration of sugars and salts relative to cells. This quality could have a harmful effect on the rectal lining by causing epithelial cells to shrink as they purge water to achieve balance. Weakened in this manner, the rectal epithelium may be less able to protect against HIV.

To make tenofovir gel safe and more amenable to rectal use, researchers from CONRAD, a research organization which holds the rights to develop the gel, reformulated it with a reduced amount of glycerin, a common additive found in many gel-like products. In laboratory tests conducted by MTN researchers, the reformulated gel was three times less likely to cause cells in rectal tissue to release water, and equally effective against HIV as the vaginal formulation.

"The lining of the rectum is much more fragile than the vaginal epithelium, so we can't be certain a product like tenofovir gel that is safe for vaginal use will be completely safe to use in the rectum," said Charlene Dezzutti, Ph.D., associate professor of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of Medicine and principal investigator of the MTN Network Laboratory. "We are very encouraged by our laboratory data that suggest the reformulated gel could be safer for rectal use. These results provide an important bridge to clinical studies, and we have already begun testing it with men and women."

The new formulation of tenofovir gel is being tested for safety and acceptability in a clinical trial called MTN-007, currently underway at three MTN-affiliated sites at the University of Pittsburgh,

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University of Alabama at Birmingham and Fenway Health in Boston. MTN-007 is follow-up to RMP-02/MTN-006, the first-ever clinical study to test the safety of vaginal tenofovir gel in the rectum. These results, which were also presented at CROI, found the gel significantly inhibited HIV in tissue samples, but that men and women in the study did not particularly like it and some experienced uncomfortable gastrointestinal side effects. Researchers are hopeful the reformulated gel now being tested in MTN-007 will address these concerns.

In addition to Dr. Dezzutti, other authors of the study are Lisa Rohan, Ph.D., University of Pittsburgh; J.D. Lynam, Magee-Womens Research Institute; Lin Wang, M.D., Ph.D., Magee-Womens Research Institute; and David Friend, Ph.D., CONRAD, Arlington, Va.

Tenofovir gel contains the antiretroviral tenofovir, which is commonly used in the treatment of HIV. Both the oral and vaginal formulations of tenofovir were developed by Gilead Sciences, Inc., of Foster City, Calif. In 2006, Gilead Sciences assigned the rights for tenofovir gel to the International Partnership for Microbicides of Silver Spring, Md., and CONRAD, of Arlington, Va.

The study was conducted through the MTN, which is funded by the National Institute of Allergy and Infectious Diseases Division of AIDS with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

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Additional information about rectal microbicides is available at http://www.mtnstopshiv.org/news/.

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.

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