CONTACT: Lisa Rossi
PHONE : +1-412-641-8940
+1-412-916-3315 (cell)
E-MAIL: rossil@upmc.edu

FOR IMMEDIATE RELEASE

SAFETY OF NEW MICROBICIDE FOR HIV PREVENTION TO BE TESTED IN YOUNG WOMEN IN U.S. TRIAL

PITTSBURGH, July 9, 2007 – Nearly half of all people infected with HIV/AIDS are now women, the majority of whom contracted the disease through sexual intercourse with male partners. Especially alarming is the steady increase in HIV rates among women under the age of 25, a population considered one of today's most vulnerable for acquiring the disease. Due to both biological and cultural factors, women are more than twice as likely as men to acquire HIV through sexual intercourse.

In an effort to help stem the tide of the HIV/AIDS epidemic, particularly in women, researchers have launched a clinical safety trial of a topical vaginal microbicide with a unique molecular structure that holds promise for preventing the sexual transmission of HIV.

The Microbicide Trials Network (MTN) is leading the National Institutes of Health-funded study in which SPL7013 Gel, or VivaGel™, is being tested for the first time in sexually active young women to determine the product's safety, acceptability and ease of use. The expanded safety study, known as MTN-004, is being conducted at the University of South Florida in Tampa and the University of Puerto Rico in San Juan through a collaboration between the MTN, an HIV/AIDS clinical trials network established by the National Institute of Allergy and Infectious Diseases, and the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) of the National Institute of Child Health and Human Development.

Vaginal microbicides are applied topically to the surface of the vagina and are designed to reduce or prevent the sexual transmission of HIV and other sexually transmitted infections. A microbicide can be formulated in many ways, such as a gel or cream. Several microbicide products are being tested in clinical trials, although none is yet approved or available for use by women.

VivaGel is thought to act by hampering the ability of HIV to attach to and infect healthy cells. Unlike other candidate microbicides, including those that target similar cell mechanisms, the active ingredient of VivaGel, belongs to a class of compounds called dendrimers. A dendrimer is a large molecular

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structure that incorporates multiple units of an active component on its surface. In the case of SPL7013, each dendrimer incorporates 32 copies of the active component. Starpharma Pty.Ltd., of Melbourne, Australia, is developing VivaGel for the prevention of both HIV/AIDS and genital herpes.

According to statistics from UNAIDS and the U.S. Centers for Disease Control and Prevention, 48 percent of the 39.5 million people living with HIV/AIDS are women, and among 15- to 24-year-olds with HIV, females account for 60 percent. In the United States, 43 percent of AIDS cases among those ages 13 to 19 are in women.

The MTN-004 study will enroll 40 sexually active, HIV-negative women between the ages of 18 and 24 years of age. Participants will be randomly assigned to one of two study groups, with neither the researchers nor the participants knowing their assignment. One group will apply VivaGel twice a day for two weeks, while participants in the other group will apply a placebo gel with no active ingredients. All women in the study will be provided condoms to be used with each act of sex.

Researchers will assess the safety of VivaGel compared with the placebo gel through laboratory tests and regular clinical examinations of study participants. Web-based questionnaires will also provide information about the product's acceptability, such as what participants liked or disliked about using the gel, how their sexual partners felt about its use and how likely they are to use microbicides in the future. Participation in the study will last three weeks, including the two-week period that gels are used.

"It's important to study the gel in young women who are sexually active because this is the very population likely to use and benefit most from this kind of HIV prevention approach," said Ian McGowan, M.D., Ph.D., professor of medicine, Center for Prevention Research at the David Geffen School of Medicine, University of California, Los Angeles. "If we are satisfied with the results in terms of the gel's safety profile we may consider conducting trials that would include more women, and eventually, look to see if the gel can help reduce their chances of acquiring HIV," added Dr. McGowan, who, in addition to serving as protocol chair of the MTN-004 study, is MTN co-principal investigator.

An earlier Phase I study of VivaGel in sexually abstinent women ages 18 to 43 found no safety concerns. In that study, women were randomly assigned to receive different doses of the gel and closely examined during a seven-day inpatient stay in a clinical research unit. Another safety study is in progress in which VivaGel's potential indication for genital herpes is being assessed.

At the site level, MTN-004 is being led by Diane Straub, M.D., M.P.H., chief of adolescent medicine and assistant professor of pediatrics at the University of South Florida; and Irma Febo, M.D., director of the Pediatric AIDS Research Program and associate professor of pediatrics at the University of Puerto Rico. MTN-004 is the first of three MTN trials expected to be launched this year.

In total, MTN anticipates conducting up to 17 scientifically rigorous and ethically sound clinical trials between 2006 and 2013. Included in its research portfolio are two ongoing trials that, until 2006, were part of NIAID's HIV Prevention Trials Network (HPTN). The first of these is HPTN 035, a multi-center clinical trial evaluating the safety and effectiveness of two different candidate microbicides, BufferGel® and PRO 2000, in 3,100 sexually active HIV-negative women at seven sites in Africa and the United States. Results, which are expected in 2009, will indicate if the candidate microbicides helped prevent HIV infection in these women. HPTN 059 is a randomized controlled trial comparing the safety and acceptability of an anti-retroviral based gel, tenofovir 1% (PMPA), used daily versus before each act of sex over a six-month period. Researchers recently completed enrollment of 200 HIV-negative women into this trial at three sites in India and the United States, and they expect to have results in early 2008.

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NOTE TO EDITORS: For more information about MTN-004 and other MTN studies, please go to www.mtnstopshiv.org.

The Microbicide Trials Network (MTN) is an HIV/AIDS clinical trials network established in 2006 by the Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). The MTN brings together international investigators, community and industry partners who are devoted to reducing the sexual transmission of HIV through the development and evaluation of microbicides, working within a unique infrastructure specifically designed to facilitate research required to support licensure of topical microbicide products for widespread use. Based at the University of Pittsburgh and Magee-Womens Research Institute, MTN's principal investigator is Sharon Hillier, Ph.D. 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 at the Fred Hutchinson Cancer Research Center, and Family Health International, a global organization with expertise conducting clinical protocols. It receives its funding from three NIH institutes: NIAID, the National Institute of Mental Health and the National Institute of Child Health and Human Development. More information can be found at www.mtnstopshiv.org.

The Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) has long been the only national network focused on studying the emerging HIV/AIDS epidemic in teens infected through sex or injecting-drug behaviors. The information derived from this network informs the nation's adolescent-specific HIV/AIDS scientific agenda to improve efforts for prevention of HIV infection among at-risk adolescents and to optimize the medical management of HIV-infected teens. Funded by the National Institute of Child Health and Human Development, part of the U.S. National Institutes of Health, the primary mission of the ATN is to conduct research, both independently and in collaboration with existing research networks, such as the Microbicide Trials Network, on promising behavioral, microbicidal, prophylactic, therapeutic, and vaccine modalities in HIV-infected and HIV-at-risk adolescents, ages 12 through 24 years. Based at the University of Alabama at Birmingham, ATN's principal investigator is Craig M. Wilson, M.D. More information is available at www.atnonline.org.