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Phase I Study Finds Candidate Microbicide VivaGel Generally Well Tolerated but Women Less Willing to Use It

PITTSBURGH, May 25, 2010 – A Phase I trial of a vaginal microbicide called VivaGel® found it was generally well tolerated yet women in the study said it was less acceptable to use than the two placebo gels, reported researchers today at the International Microbicides Conference (M2010) in Pittsburgh.

"These findings suggest that it may be necessary to consider reformulating VivaGel before moving to Phase 2 studies," said Ian McGowan, M.D., Ph.D., professor of medicine in the division of gastroenterology, hepatology and nutrition at the University of Pittsburgh School of Medicine, who led the National Institutes of Health (NIH)-funded study for the Microbicide Trials Network (MTN). Dr. McGowan is MTN co-principal investigator.

Microbicides are substances intended to reduce or prevent the sexual transmission of HIV and other sexually transmitted infections when applied topically inside the vagina or rectum. A microbicide can be formulated in many ways, such as a gel or in a vaginal ring. Several candidate microbicides are being tested in clinical trials, although none is yet approved or available for use.

The active ingredient in VivaGel, SPL7013, is from a relatively new class of compounds called dendrimers that block HIV from getting near to or attaching to cells. The study was conducted to determine the safety and acceptability of the product before progression to further testing.

Women are fast becoming the group hardest hit by the HIV/AIDS epidemic. 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. According to statistics from UNAIDS, half of the more than 33 million people living with HIV/AIDS worldwide are women, and among 15- to 24-year-olds with HIV, females account for about 60 percent of the total. In the United States, girls represented 41 percent of AIDS cases reported among people aged 10 to 24, according to the most current information from the U.S. Centers for Disease Control and Prevention.

Specifically, the study was designed to assess the safety, adherence, acceptability, and effect on vaginal microflora (bacteria and other microorganisms that are important to the health of the vagina). A total of 61 sexually active women aged 18-24 were enrolled and randomly assigned to one of three treatment groups: 22 women received VivaGel; 21 women received a VivaGel placebo, formulated in the same way but without the active ingredient; and 18 women in the third group received a placebo gel known as hydroxyethyl cellulose

(HEC), which also contains no active microbicide and was used as an additional comparison. The participants inserted the vaginal gel twice daily for 14 consecutive days.

None of the women experienced a serious side effect or withdrew from the study due to any kind of side effect. Genital signs and symptoms, including vaginal itching, burning or redness, were reported most frequently with VivaGel (63.6 percent) compared with the VivaGel placebo (52.4 percent) and HEC placebo (38.9 percent), although these differences were not statistically significant. In a head-to-head comparison between products, however, women in the VivaGel group had a significantly higher incidence of urological-gynecological side effects compared to the HEC placebo group. Abnormal genital findings found on pelvic exam, however, occurred relatively infrequently and were reported in similar proportions of women in all groups. Both VivaGel and the VivaGel placebo caused changes to the bacteria that normally exist in the vagina but twice daily use for 14 days did not result in vaginal infections such as bacterial vaginosis.

Women using VivaGel were less adherent to product use than women in the other two groups, with adherence rates 77 percent for VivaGel, 95 percent for the VivaGel placebo and 94 percent for the HEC placebo group, although this included times when women were told not to use the product. Women also reported they were less likely to use VivaGel – 36 percent in that group said they would be very likely to use the gel again in the future, while 48 percent of the women in the VivaGel placebo group and 61 percent of those in the HEC placebo group reported they would be likely use those products again.

MTN-004 was conducted at the University of South Florida in Tampa and the University of Puerto Rico in San Juan in a collaboration between the MTN and the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) of NICHD. A third site was at the University of Pittsburgh, a clinical research site affiliated with the MTN. MTN is an HIV/AIDS clinical trials network established by the U.S. National Institute of Allergy and Infectious Diseases (NIAID) with co-funding from the National Institute of Mental Health (NIMH) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD).

In addition to Dr. McGowan, other authors of the study presented at M2010 are: Kailazarid Gomez, MPM, Family Health International; Patricia Emmanuel, M.D., University of South Florida; Irma Febo, M.D., University of Puerto Rico; Beatrice A. Chen, M.D., University of Pittsburgh School of Medicine; Barbra Richardson, Ph.D., University of Washington and Fred Hutchinson Cancer Research Center; Marla Husnik, M.S., also of the Fred Hutchinson Cancer Research Center; Edward Livant, BSMT (ASCP), MPH, of the MTN and Magee-Womens Research Institute; Jeanna M. Piper, M.D., Division of AIDS, NIAID; and Clare Price, Starpharma Pty Limited, of Melbourne, Australia, which is developing VivaGel and provided the study product for MTN-004.

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More information about MTN-004 and other MTN studies is available at http://www.mtnstopshiv.org/news