



**For Immediate Release
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FDA and CONRAD Chart U.S. Regulatory Path for 1% Tenofovir Gel for HIV Prevention

Collaborative meeting held with key stakeholders

Arlington, VA - - The U.S. Food and Drug Administration (FDA) held an end-of-Phase II meeting to determine the next steps required for U.S. licensure of 1% tenofovir gel, a microbicide product recently found to be effective at reducing the rate of HIV and herpes infection in women when used before and after sex.

The meeting, held on October 20, 2010, was requested by CONRAD, a division of the Eastern Virginia Medical School in Norfolk, VA. CONRAD was one of the partners in the Phase II study, "CAPRISA 004," which evaluated 1% tenofovir gel in prevention of male-to-female HIV transmission in 889 women in South Africa. USAID provided funding for the trial, conducted by the Centre for Programme Research for AIDS in South Africa and U.S. based FHI, which was the first study to show that a vaginal gel can reduce the risk of HIV and herpes infection in women. CONRAD manufactured and provided the tenofovir gel for the study.

Tenofovir gel was found to be 39% effective in reducing a woman's risk of becoming infected with HIV during sex and 51% effective in preventing genital herpes infections in the women participating in the trial. Results of the CAPRISA 004 clinical trial were reported in July 2010 and represent the first "proof of concept" for a vaginal microbicide.

A number of key stakeholders contributed to the collaborative meeting with the FDA, including representatives from the U.S. National Institutes of Health, the U.S. Agency for International Development, Gilead Sciences, Microbicides Trial Network (MTN), South African clinical investigators, the International Partnership for Microbicides (IPM) and FHI.

During the meeting, the FDA stated their preference for two well-controlled studies to verify the safety and efficacy of 1% tenofovir gel prior to submission of a New Drug Application (NDA). The FDA furthermore stated that the NIH-sponsored Phase IIB study, MTN-003, known as VOICE (Vaginal and Oral Interventions to Control the Epidemic), represents a second adequate and well-controlled study that would, if successful, serve as the second pivotal trial together with CAPRISA 004 to support the submission of an NDA for 1% tenofovir gel.

In addition, the FDA has granted Fast Track approval designation for 1% tenofovir gel, which facilitates the development and expedites the review of drugs that are intended for treating serious diseases and fill an unmet medical need. With Fast Track designation, an NDA can be submitted as a “rolling review”, which allows a clinical trial sponsor to submit completed sections of its NDA for review by the FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

The agency agreed that the current preclinical program for 1% tenofovir gel is sufficient to support a future NDA. However, they stated that additional safety data on adolescents would be needed and that information on in vivo drug interaction studies with commonly used vaginal products should be obtained. Also, the FDA will ultimately need data on post menopausal women. It was also agreed that a future meeting with the FDA would be held to address any outstanding discussions associated with product quality, including chemistry, manufacturing and controls (CMC). Since much of the clinical work on 1% tenofovir gel has been and will be conducted in South Africa, FDA officials indicated that they can work through the FDA’s “Office of International Programs” with the goal of coordinating the data and review processes with the South African Medicines Control Council.

CONRAD and its partners appreciate the contributions and detailed recommendations put forth by the FDA, which have helped clarify the next steps required for testing and licensure of 1% tenofovir gel.

In 2006, CONRAD and IPM obtained a co-exclusive, royalty-free license from Gilead Sciences to develop 1% tenofovir gel as a topical microbicide for use by women in developing countries to prevent HIV.

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***CONRAD** (www.conrad.org) was established in 1986 and is a Division of the Department of Obstetrics and Gynecology at Eastern Virginia Medical School (EVMS) in Norfolk, VA, where it has laboratories and a clinical research center. The main office is located in Arlington, VA with additional offices in West Chester, PA and collaborators around the world. CONRAD is committed to improving reproductive health by researching and developing new contraceptive options and products to prevent HIV and STI infections.*