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Phase III Trial of Cellulose Sulfate Microbicide for HIV Prevention Closed

Research Triangle Park, NC – Family Health International (FHI) announced today that it has halted a Phase III clinical trial of cellulose sulfate -- a potential microbicide being tested for HIV prevention in women -- in Nigeria. Simultaneously, CONRAD, a health research organization based in Arlington, Virginia, has announced it is halting its Phase III clinical trial of cellulose sulfate at sites in Benin, India, South Africa, and Uganda.

Cellulose sulfate (CS) was one of four microbicide candidates in Phase III effectiveness trials for prevention of HIV and other sexually transmitted infections. A review of the preliminary results of CONRAD's cellulose sulfate trial by an Independent Data Monitoring Committee (IDMC) for CONRAD's study determined that cellulose sulfate use could lead to an increased risk of HIV infection.

Separately, Family Health International decided to close its cellulose sulfate study in Nigeria after the Data Monitoring Committee (DMC) for the FHI study -- an independent advisory group of experts -- reviewed the interim results from CONRAD's cellulose sulfate study. FHI's DMC also reviewed interim data from FHI's Nigeria study and found no evidence of increased risk of HIV infection.

"In Nigeria we did not find any evidence of greater risk of HIV infection," said Dr. Vera Halpern, principal investigator of FHI's trial. "But we also found no evidence that the product was effective in preventing HIV. Given the disappointing results from CONRAD's study of the same microbicide candidate in other countries, the responsible course of action was to halt our study."

Cellulose sulfate was assessed in multiple safety trials before entering Phase III HIV prevention trials. The gel, also known as Ushercell, is a cotton-based compound developed by Polydex Pharmaceuticals, based in Toronto, Canada. Prior to the Phase III HIV prevention trials implemented by Family Health International and CONRAD, cellulose sulfate had been evaluated in 11 rigorous clinical safety and contraceptive trials involving more than 500 participants. Eight of those trials were conducted in the United States. Evidence from those early animal and human studies indicated that cellulose sulfate had a strong safety profile with minimum vaginal irritation; in laboratory studies, cellulose sulfate exhibited antimicrobial activity against several sexually transmitted infections, including HIV.

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FHI's study was conducted among almost 1,700 women in Lagos and Port Harcourt, Nigeria. All participants will be asked to return to the study sites so that study staff can inform them that the study has been closed and answer any questions they have. During these closeout visits, study staff will collect all unused gel supplies and provide counseling, testing for sexually transmitted infections, HIV, and pregnancy, and referrals for medical care. The study sites will remain open for several months to ensure that all participants receive the information they need and to complete the necessary study follow-up and safety monitoring.

During the study, participants received HIV prevention counseling, condoms, and, when needed, treatment for sexually transmitted infections. Women who became infected with HIV during the trial were referred to local facilities that offer HIV-related psychological, social, and medical services. During the closing period, study staff will continue to refer women who test HIV-positive to these facilities. The site investigators have written agreements in place with programs supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in Lagos to provide care to HIV-infected study participants, including antiretroviral treatment as needed.

Jeff Spieler, Chief of Research, Technology and Utilization Office of Population and Reproductive Health at the United States Agency for International Development, which funded the FHI study and co-funded the CONRAD study, said, "I am surprised and disappointed by the findings of the CONRAD study, given the pre-clinical effectiveness profile of cellulose sulfate against HIV and other sexually transmitted infections and its safety profile demonstrated in Phase I trials. I cannot think of any biological basis for these findings, and I hope that further analysis of all of the data may shed further light on this important question."

It is imperative to continue support for ongoing effectiveness trials and for the development of other microbicide candidates in the research pipeline. Microbicides are urgently needed to provide a woman-controlled HIV prevention option because women are socially and biologically more vulnerable than men are to the HIV virus. In Africa, almost 60 percent of new infections are acquired by women and girls.

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Family Health International (FHI) is a nonprofit organization dedicated to improving lives, knowledge and understanding worldwide through a highly diversified program of research, education, and services in family health and HIV/AIDS prevention and care. Since its inception in 1971, FHI has formed partnerships with national governments and local communities in countries throughout the developing world to support lasting improvements in the health of individuals and the effectiveness of entire health systems. For more information, see: www.fhi.org