Two-Drug Vaginal HIV Microbicide Ring Enters U.S. Safety Study

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For the first time ever, researchers are conducting a clinical trial evaluating the safety of a vaginal ring combining two antiretroviral (ARV) medications that may prove to be more effective and easier to use than microbicide gels. The study, being conducted by the Microbicide Trials Network (MTN) and the International Partnership for Microbicides, is now screening participants at three sites in the United States.

The study, MTN-013/IPM 026, is being funded by the U.S. National Institutes of Health and involves a vaginal ring containing Janssen Therapeutics' non-nucleoside reverse transcriptase inhibitor dapivirine (TMC120)—tested initially as an oral medication to treat HIV—along with maraviroc, ViiV Healthcare's CCR5-blocking entry inhibitor and the active ingredient in Selzentry.

The dapivirine-maraviroc ring is the first combination microbicide to enter clinical trials and the first vaginal microbicide to contain an entry inhibitor, according to a press release issued by the University of Pittsburgh, one of three U.S. sites conducting the study. Other sites include the Fenway Institute in Boston and the University of Alabama in Birmingham.

The ring was developed by IPM, a nonprofit product development partnership headquartered in Silver Spring, Maryland, in collaboration with Queens University Belfast in Northern Ireland. The belief is that combining the two drugs, which act at different points in the HIV "life cycle," may provide greater protection against HIV than a single drug alone.

Globally, women comprise half of the 34 million people living with HIV. In sub-Saharan Africa, women represent nearly 60 percent of adults with the virus. In most cases, women—particularly young women—acquire HIV through unprotected heterosexual sex with an HIV-positive partner. Because women often can't control whether their partners use condoms, there is an urgent need for effective prevention strategies that women can control themselves. As a result, vaginal microbicides in the form of a gel or a ring are being developed to provide women with new tools to protect themselves against HIV.

Compared with gels the must be applied daily or immediately before sex, vaginal rings' major advantage is that they provide slow, continuous delivery of a drug or multiple drugs to cells inside the vagina over a period of weeks or months. The rings, which will be worn inside the vagina for 28 days, are made of silicone and are about 2.25 inches in diameters and are a quarter of an inch

thick.

For the study, 48 HIV-negative women between ages 18 and 40 are being screened. The MTN-013/IPM 026 researchers will evaluate the ring’s safety and how well women like or are willing to use the ring. In addition, different tests will help determine how much of each drug is taken up by the cells usually targeted by HIV and whether drug levels are sustained throughout the four weeks the ring is worn.

Women will be randomly assigned to use either the combination dapivirine-maraviroc ring, a ring containing maraviroc alone, a ring that contains dapivirine alone, or one with no active drug. This will enable researchers to compare the safety and drug delivery capability of the combination ring with each single-drug ring and with the placebo ring.
MTN-013/IPM 026 is expected to take less than a year to complete with results available in early 2013.

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