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FOR IMMEDIATE RELEASE

Phase III Trial of Dapivirine Ring Begins in Africa: ASPIRE testing new HIV prevention approach for women

WASHINGTON, D.C., July 24, 2012 – A large clinical trial testing the long-term safety and effectiveness of a new approach for preventing HIV in women – a vaginal ring used once a month – is now underway in Africa, researchers announced today at the XIX International AIDS Conference (AIDS 2012).

ASPIRE – A Study to Prevent Infection with a Ring for Extended Use – is a Phase III trial evaluating a vaginal ring that contains dapivirine, a potent antiretroviral (ARV) drug originally developed to treat HIV. The ring slowly releases dapivirine to cells inside the vagina throughout the one-month period that it's worn, potentially giving women discreet, long-acting protection against HIV transmitted through sex.

Nearly 3,500 women in Africa will take part in ASPIRE, which is being led by the Microbicide Trials Network (MTN) and funded by the National Institute of Allergy and Infectious Diseases and the National Institute of Mental Health, which are part of the U.S. National Institutes of Health. Makerere University-Johns Hopkins University Research HIV Clinical Trial Unit in Kampala, Uganda this week began screening women interested in joining the study. A second site, the Emavundleni Research Center at the Desmond Tutu HIV Foundation, University of Cape Town, South Africa, should be ready to screen potential participants next week. The MTN hopes to conduct ASPIRE at a total of 17 sites in Malawi, Uganda, South Africa, Zambia and Zimbabwe.

A second trial, The Ring Study, is being conducted in parallel with ASPIRE. The Ring Study is being led by the International Partnership for Microbicides (IPM), which developed the dapivirine ring, and will involve about 1,650 women. IPM has already enrolled nearly 400 participants at trial sites in South Africa since the study began in April. The Ring Study will also be conducted in Rwanda and is expected to start there in August.

The two sister studies are the first effectiveness trials of a vaginal ring for HIV prevention. Vaginal rings, which are flexible products that fit comfortably high up inside the vagina and are seldom felt by either partner during sex, are already used in many countries as a way to deliver hormonal contraception.

ASPIRE and The Ring Study are also the first large-scale prevention trials involving an ARV other than tenofovir or a tenofovir combination. For this reason, and because it is used for a month at a time, the dapivirine ring is seen as an alternative to tenofovir gel used daily or at the time of sex, and oral pre-exposure prophylaxis (PrEP), which involves the use of a daily ARV tablet – tenofovir or Truvada (tenofovir plus emtricitabine).

"As a field, we must continue to develop new strategies for HIV prevention. No single approach will be right for every person. In the same way there is a range of effective choices when it comes to birth control, women must have multiple effective options for HIV prevention," explained Jared Baeten, M.D., Ph.D., of the University of Washington in Seattle, who is leading ASPIRE with Thesla Palanee, Ph.D., of the Wits Reproductive Health and HIV Institute (WRHI) in Johannesburg, South Africa.

"The most effective HIV prevention product can only work if it's used consistently. The recent PrEP and microbicide studies have taught us that using a product every day can be challenging for many people. A sustained delivery product like a vaginal ring can release an antiretroviral drug in the vagina over an entire month following a single insertion. We think this will be an attractive option for many women, and we hope that women in ASPIRE will like the ring and use it consistently," added Sharon Hillier, Ph.D., principal investigator of the MTN, which is based at the University of Pittsburgh School of Medicine and Magee-Womens Research Institute.

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ASPIRE is designed to enroll approximately 3,476 HIV-negative women between the ages of 18 and 45 who will be randomly assigned to use either the dapivirine ring or a placebo ring that looks the same but contains no active drug. Participants will be instructed how to insert and remove the ring, which they will replace every four weeks over the course of the one to two years they are in the study. All participants will receive ongoing HIV risk reduction counseling, condoms and diagnosis and treatment of sexually transmitted infections (STIs).

The results of ASPIRE, which are expected late 2014 or early 2015, together with results of The Ring Study, as well as smaller, supporting studies, will form the basis of an application that IPM plans to submit to regulatory authorities seeking approval of the dapivirine ring for widespread use.

"Through IPM's partnership with MTN and NIH, we are able to conduct two pivotal studies in parallel and get the answers we need quickly," said Zeda Rosenberg, Sc.D., chief executive officer of IPM, a nonprofit product development partnership based in Silver Spring, Md. "Regulators usually require results of two large-scale Phase III trials, along with data from other supporting studies, to approve a product for use. This unique collaboration aims to help us make dapivirine ring available as quickly as possible to women in developing countries if it is proven effective and safe for long-term use."

Of the more than 34 million people living with HIV, half are women; and women account for 59 percent of adults with HIV in sub-Saharan Africa, where unprotected heterosexual intercourse is the primary driver of the epidemic. Young women are especially vulnerable; women ages 15 to 24 are up to five times more likely to become infected with HIV than young men. Efforts to promote abstinence, monogamy and the use of male condoms have not been enough to stop the HIV epidemic nor are these practical methods in many settings.

IPM is developing dapivirine for use as a microbicide through a royalty-free licensing agreement with Janssen R&D Ireland (previously Tibotec Pharmaceuticals), one of the Janssen pharmaceutical companies of Johnson & Johnson. Dapivirine, also known as TMC-120, belongs to a class of ARVs called non-nucleoside reverse transcriptase inhibitors (NNRTIs) that bind to and disable HIV's reverse transcriptase enzyme, a protein that HIV needs to make copies of itself.

In addition to the Uganda and Cape Town, South Africa sites, ASPIRE will be conducted at the following MTN-affiliated trial sites, pending all necessary approvals: In Malawi – the University of North Carolina Clinical Research Site in Lilongwe and the College of Medicine-Johns Hopkins University Research Project at Queen Elizabeth Central Hospital in Blantyre; in South Africa – the Medical Research Council of South Africa in KwaZulu-Natal (seven sites), the eThekwini site for the Centre for the AIDS Programme in Research in South Africa (CAPRISA) in Durban; WRHI in Johannesburg; in Zambia – the Centre for Infectious Diseases Research in Zambia in Lusaka; and, in Zimbabwe – the University of Zimbabwe-University of California, San Francisco HIV Prevention Trials Unit in Harare (three sites).

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More information about ASPIRE is available at http://www.mtnstopshiv.org/news/studies/mtn020 and about The Ring Study at http://www.ipmglobal.org/the-ring-study.

About the Microbicide Trials Network

The Microbicide Trials Network (MTN) is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. Based at Magee-Womens Research Institute and the University of Pittsburgh, the MTN brings together international investigators and community and industry partners who are devoted to preventing or reducing the sexual transmission of HIV through the development and evaluation of products applied topically to mucosal surfaces or administered orally.

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