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FOR IMMEDIATE RELEASE

Researchers complete ASPIRE Phase III trial of the dapivirine vaginal ring for HIV prevention in women; results are expected early 2016

PITTSBURGH, June 29, 2015 – In a first for HIV prevention, an international team of researchers have completed follow-up of participants enrolled in a pivotal Phase III trial that tested the safety and effectiveness of a vaginal ring for preventing HIV in women. Results of the study, called ASPIRE, are expected to be reported early 2016.

ASPIRE – A Study to Prevent Infection with a Ring for Extended Use – involved 2,629 women from 15 trial sites in Malawi, South Africa, Uganda and Zimbabwe and was conducted by the U.S. National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN).

ASPIRE is one of two Phase III trials of the vaginal ring, which contains an antiretroviral (ARV) drug called dapivirine. The other trial, called The Ring Study, is being conducted by the International Partnership for Microbicides (IPM), which developed the monthly dapivirine ring.

Because women use the ring for a month at a time, the approach could feasibly offer women long-acting, discreet protection against HIV.

ASPIRE began in August 2012, and follow-up of all participants was completed on June 25, 2015. Women in the study used their assigned ring (placebo ring or a dapivirine ring) monthly for at least one year. Those who enrolled earlier in the study had used their assigned ring for up to 34 months at the time they exited the study.

The Ring Study began in April 2012 and enrolled 1,959 women at seven research centers – six in South Africa and one in Uganda. Unlike ASPIRE, women enrolled in The Ring Study are asked to remain in the study for two years because one of the study’s main objectives is to evaluate the long-term safety of the ring. Efficacy and preliminary safety results of The Ring Study are also expected early 2016.

As sister studies, ASPIRE and The Ring Study are designed to provide the strength of evidence to support potential licensure of the dapivirine vaginal ring for preventing HIV in women. Because at least two Phase III efficacy trials are usually needed for a product to be considered for regulatory approval, ASPIRE and The Ring Study were conducted in parallel to accelerate the timeline to the ring’s potential approval.

Several studies have shown that ARVs are highly effective in preventing HIV. At the same time, some studies – such as VOICE, and more recently, FACTS 001 – indicate that for young, high-risk women in Africa, ARVs delivered as a vaginal gel or as a tablet may not be the most acceptable methods. Products must be used to be effective, and that was not the case for many of the participants in these studies.

Vaginal rings are flexible products that fit comfortably high up inside the vagina where they release a medication slowly over time. They are already used in many countries to deliver hormonal contraception. The dapivirine ring adapts that medical technology by using an ARV instead of contraception as a way to offer women potentially long-acting protection against HIV. Women can insert and replace the ring themselves.

“It has been a privilege to take part in ASPIRE. Everyone who has played a role in the conduct of ASPIRE – the entire study team, all our study participants and the communities where ASPIRE took place – has reason to be proud of the tremendous accomplishments this study represents for the field,” said Jared Baeten, M.D., Ph.D., of the University of Washington, who as protocol chair is leading the trial for the MTN.

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“We are hopeful that the women who took part in ASPIRE, as well as participants in The Ring Study, found the ring acceptable to use. In order to curb the rate of HIV infections in young African women, we need to find a prevention method that is easily incorporated into their lives. The dapivirine ring has enormous potential to be that method,” said Thesla Palanee, Ph.D., ASPIRE protocol co-chair who also directs the study at her own institution, the Wits Reproductive Health and HIV Institute (Wits RHI) in Johannesburg, South Africa.

Plans are underway for an open-label extension trial called HOPE (HIV Open-label Prevention Extension), or MTN-025, in which former participants would be able to use the dapivirine ring for approximately one year. Whether that study moves forward will depend on the outcome of ASPIRE. As a research study, HOPE would gather additional data on the safety of and adherence to the ring, information that would help understand issues important for broader implementation of the ring should it receive regulatory approval.

Pending results of ASPIRE and The Ring Study, along with other smaller supporting studies, IPM, as the dapivirine ring’s developer and regulatory sponsor of the Phase III program, will seek regulatory approval to license the ring.

Some of the supporting studies include trials conducted by the MTN at U.S. clinical research sites. MTN-024/IPM 031 looked at the ring’s safety and drug absorption in post-menopausal women. A similar study in adolescent girls, MTN-023/IPM 030, is being conducted in collaboration with the Adolescent Trials Network for HIV/AIDS Interventions. Among IPM’s completed or ongoing studies are those looking at condom functionality, possible drug interactions and effects of menses and tampon use.

The ring’s development was made possible by a public-private partnership with Janssen Sciences Ireland UC, a Janssen pharmaceutical company of Johnson & Johnson, which granted IPM a royalty-free license in 2004 to develop dapivirine as a microbicide for women in developing countries. That license has since expanded to a worldwide rights agreement. 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 key protein needed for HIV replication.

Of the more than 35.3 million people living with HIV, more than half are women. Women account for nearly 60 percent of adults with HIV in sub-Saharan Africa, where unprotected heterosexual sex is the primary driver of the epidemic. Young women are especially vulnerable — women ages 15 to 24 are up to eight times as likely as young men to be infected with HIV. 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 most settings.

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More information about ASPIRE can be found at <http://www.mtnstopshiv.org/news/studies/mtn020> . More information about The Ring Study and the dapivirine ring can be found 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 whose work is focused on the development and rigorous evaluation of promising microbicides – products applied inside the vagina or rectum that are intended to prevent the sexual transmission of HIV – from the earliest phases of clinical study to large-scale trials that support potential licensure of these products for widespread use. More information about the MTN is available at <http://www.mtnstopshiv.org>.