

# **ASPIRE Phase III trial of vaginal ring to prevent HIV completes enrollment of 2,629 women**

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ASPIRE, one of two Phase III trials of a promising method for preventing HIV in women – a vaginal ring worn for a month at a time – has completed enrollment of participants, with 2,629 women from 15 clinical research sites in Malawi, South Africa, Uganda and Zimbabwe now taking part in the study. ASPIRE, a flagship study of the Microbicide Trials Network (MTN), and its sister trial, The Ring Study, which is being led by the International Partnership for Microbicides (IPM), are the first to evaluate the effectiveness of a vaginal ring for HIV prevention. Both studies are testing a vaginal ring that contains an antiretroviral (ARV) drug called dapivirine.

In reaching this milestone, ASPIRE – A Study to Prevent Infection with a Ring for Extended Use, also known as MTN-020, is on target to conclude about one year from now with results expected by late 2015 or early 2016. The study was launched in August 2012.

"This is a tremendous achievement and a testament to the incredible commitment of the teams at each and every trial site. Importantly, having completed enrollment brings us that much closer to determining whether the dapivirine ring is safe and effective in women, who in many settings face tremendous HIV risk," said Jared Baeten, M.D., Ph.D., of the University of Washington, who as protocol chair is leading the trial for the MTN, both of which are funded by U.S. National Institutes of Health (NIH).

The dapivirine ring was developed by IPM, which is also the regulatory sponsor and license holder of the product. IPM's The Ring Study, also known as IPM 027, began in April 2012 and will enroll approximately 1,950 women at seven sites in South Africa and Uganda. It is expected to conclude in and have results by 2016. Because at least two Phase III efficacy trials are usually needed for a product to be considered for regulatory approval, IPM and MTN partnered to run the two sister studies concurrently to accelerate the timeline to the ring's potential approval.

Vaginal rings are flexible products that fit comfortably high up inside the vagina and provide sustained delivery of active agents over a period of time. Vaginal rings are already used in many countries to deliver hormonal contraception. The dapivirine ring adapts that medical technology as a way to offer women potentially long-acting protection against HIV. It is the first long-acting ARV-based product to enter efficacy testing and the first involving an ARV other than tenofovir or a tenofovir combination. Moreover, unlike tenofovir, dapivirine is not a drug used in the treatment of HIV.

"Perhaps the most attractive aspect about a [vaginal ring](#) as an HIV prevention method is that women can use it discreetly and use it up to a month at a time due to the slow release of the medication it contains. If the women in our trial find it easy and practical to use consistently, this will be extremely important, because only if it is used as directed are we able to assess its true effectiveness," 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..

ASPIRE is completing enrollment with fewer participants than originally planned. The research team had assumed needing to enroll up to 3,476 women to answer the study's primary questions about safety and

effectiveness, a calculation based in part on a background HIV incidence rate of 3.9 percent in trial site communities at the time the protocol was being developed. In March 2013, however, when ASPIRE was already seven months into the study, results were reported of another HIV prevention trial called VOICE indicating the HIV incidence in a very similar population was much higher, at 5.7 percent. Adjusting for both the higher HIV incidence as well as the fact that the study has more women than expected using the ring well beyond one year, the team determined a target enrollment of 2,600 participants would be sufficient to meet its objectives. Because the ASPIRE protocol was designed to accommodate new information as it becomes available, both the Study Monitoring Committee and the independent Data Safety and Monitoring Board (DSMB) that conducts routine reviews of the study were in agreement with the team. Indeed, at its most recent review on May 31, the DSMB recommended that the study, with 2,555 women enrolled to date, could stop screening new women and close enrollment soon thereafter.

When ASPIRE concludes in June or July 2015, all women will have used their assigned study product (placebo ring or dapivirine ring) for at least one year, a regulatory requirement, and some women will have used the ring two years or longer. (Because one of the main objectives of The Ring Study is to evaluate long-term safety of the ring, all women enrolled in that trial will use the monthly ring for two years.)

IPM will seek regulatory approval and licensure for the ring based on the results of The Ring Study and ASPIRE as well as several smaller safety studies taking place in the United States and Europe. A nonprofit product developer based in Silver Spring, Md., IPM is developing dapivirine for use as a vaginal microbicide in developing countries through a royalty-free licensing agreement with Janssen R&D Ireland.

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. The dapivirine ring, made of a flexible silicone material, allows the drug to be slowly released from the ring over time. IPM's studies have shown that the ring can deliver dapivirine to vaginal tissue for a month or longer, with minimal concentration elsewhere in the body. Its studies to date have also shown that use of the dapivirine ring is safe and well-tolerated by women and also acceptable to them.

Globally, women account for more than half of the more than 35 million people living with HIV/AIDS. In sub-Saharan Africa, six out of 10 new HIV infections in adults occur in women. In several southern African countries, young women aged 15 to 24 are up to eight times more likely than their male peers to be infected with HIV. Among women, unprotected sex with an infected male partner remains the primary risk factor for HIV infection, and in many parts of the world, heterosexual intercourse is the driving force of the epidemic. Women are twice as likely as their male partners to acquire HIV during sex. Although correct and consistent use of male condoms has been shown to prevent HIV infection, often [women](#) are not able to choose if they are used.

**More information:** More information about ASPIRE can be found at [www.mtnstopshiv.org/news/studies/mtn020](http://www.mtnstopshiv.org/news/studies/mtn020)

Provided by Microbicide Trials Network

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