

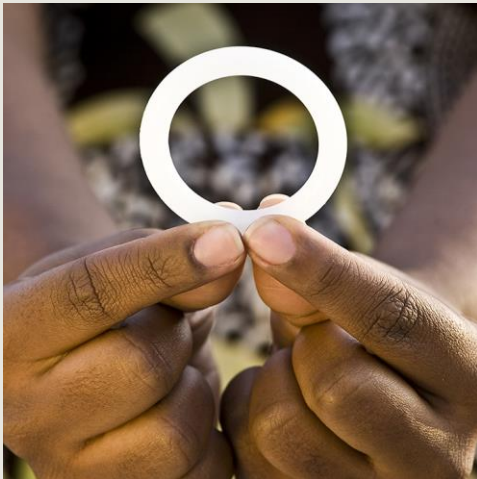
Preparing for Results: The Dapivirine Ring

A promising new HIV prevention tool for women

By early 2016, late-stage clinical trial results will reveal whether an innovative HIV prevention technology — the dapivirine vaginal ring — can help keep women safe from infection. If the monthly ring is found effective and safe for long-term use, it could help overcome one of the greatest challenges of the AIDS epidemic: protecting women.

The International Partnership for Microbicides (IPM) developed the ring and advanced the product from concept to late-stage trials in just seven years. The dapivirine ring is now in two Phase III trials involving thousands of women across Africa. 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 the antiretroviral (ARV) drug dapivirine as a microbicide for women in developing countries. That license has since expanded to a worldwide rights agreement.

The dapivirine ring could address a major unmet need for women: **a long-acting, discreet HIV prevention option**



Women and HIV/AIDS

Why prioritize HIV prevention for women?

Despite global progress in the last decade, women in low- and middle-income countries still bear a disproportionate burden of HIV/AIDS, which is the leading cause of death globally among women ages 15-44.¹ It exacts an especially high toll in sub-Saharan Africa, where young women are at least twice as likely to be infected as young men.²

Existing prevention tools are not enough

Women are particularly vulnerable to HIV infection due to biology and widespread gender inequality, which often limits their ability to negotiate condom use with partners.³

Women urgently need a toolkit of safe and discreet HIV prevention options that meet their needs and preferences — from long-acting rings and injectable ARVs to oral ARV pills (PrEP) and a vaccine.

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The Dapivirine Ring: Transforming HIV Prevention

The dapivirine ring is a vaginal microbicide made out of flexible silicone designed to provide sustained release of dapivirine to help protect against HIV infection. Women would replace the ring themselves every month. The latest research shows that ARVs can prevent HIV in women when they are used consistently.

What is dapivirine?

Dapivirine is a potent ARV drug that belongs to the same class of ARVs already being used successfully to treat people with HIV and to prevent mother-to-child transmission. Seventeen IPM clinical studies have found dapivirine and the ring to be safe, acceptable and well-tolerated.

A Pivotal Milestone: Phase III Trials

Following our Phase I and II safety studies of the ring in 2010-2012, IPM advanced the product to two parallel Phase III trials to shorten the time between research and potential regulatory approval. IPM and its clinical trial partner, the National Institutes of Health-funded Microbicide Trials Network (MTN), are each leading one of these simultaneous “sister studies” to test the ring’s efficacy and long-term safety: The Ring Study (led by IPM) and ASPIRE (led by MTN). It is hoped that results from these two large studies along with data from smaller supporting studies — all expected later this year or in early 2016 — will supply the evidence needed to begin putting the dapivirine ring in women’s hands.

From concept to Phase III

The dapivirine ring’s path from concept to late-stage clinical trials:

- **2004:** IPM begins preclinical work to develop the dapivirine ring
- **2005-2010:** IPM adapts existing ring technology to the fight against HIV, selecting one of four novel prototypes designed and tested during this period
- **2010-2012:** IPM completes three Phase I/II safety trials of the dapivirine ring in Africa and Belgium
- **2012:** Parallel Phase III trials launch—The Ring Study and ASPIRE
- **Early 2016:** Phase III trial results expected

Planning for Access

IPM is working with partners to ensure the dapivirine ring is available and affordable to women in developing countries as soon as possible should it be proven effective. Work under way includes:

- Consulting global, regional and national regulatory experts
- Assessing manufacturing capacity and anticipated demand
- Educating health providers and communities
- Identifying partners for future country-by-country product roll-out
- Securing funds to support the implementation of access strategies

Next-Generation Dapivirine Rings

IPM is leveraging the innovative ring technology to develop other products. These include a three-month dapivirine-contraceptive ring to enter a Phase I trial in 2015 as well as a two-month combination ARV ring.

¹ WHO, “[Women’s health](#),” 2013

² UNAIDS, [Report on the Global AIDS Epidemic](#), 2013

³ WHO, “[Gender inequalities and HIV](#),” 2013