IPM: Pioneering HIV prevention options for women

INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

Fifteen years ago, the International Partnership for Microbicides (IPM) entered the HIV prevention field with a promise and a clear vision to create products that women in developing countries could use themselves to prevent HIV, and protect their sexual and reproductive health. Every step we have taken since then has brought that vision into sharper focus. Today, we are as optimistic about our mission as we have ever been.

The HIV/AIDS epidemic continues to disproportionately affect women in developing countries. Currently available options are often unrealistic for many women, who urgently need practical, self-initiated tools they can and are willing to use. IPM's monthly dapivirine ring and other technologies in development could help empower women with discreet and long-acting tools they can use to protect their own health.

Our Progress

Since IPM was founded as a nonprofit organization in 2002, we have leveraged public, philanthropic and private sector resources to accelerate the development of safe and effective life-saving technologies for women.

IPM builds on partnerships — with governments, foundations, researchers, pharmaceutical companies, policymakers, advocates and communities — to bring scientific ingenuity, political will and financial resources to bear on all phases of product development. Our key achievements include:

- **Developing the first effective, long-acting HIV prevention product for women: the monthly dapivirine ring**

IPM led the development and testing of the dapivirine ring, the first long-acting HIV prevention method shown to safely help offer protection. The novel vaginal ring delivers the antiretroviral (ARV) drug dapivirine continuously over the course of one month, offering women a practical and discreet way to protect themselves against HIV. By marshalling scientific know-how and resources through partnerships with public, private, research and civil society stakeholders, we brought the ring from concept to Phase III efficacy trials just seven years after acquiring the license for dapivirine. In 2016, two parallel Phase III trials confirmed the safety and efficacy of IPM's monthly dapivirine ring.

IPM's monthly dapivirine ring

- **Negotiating innovative licenses to acquire potent ARVs**

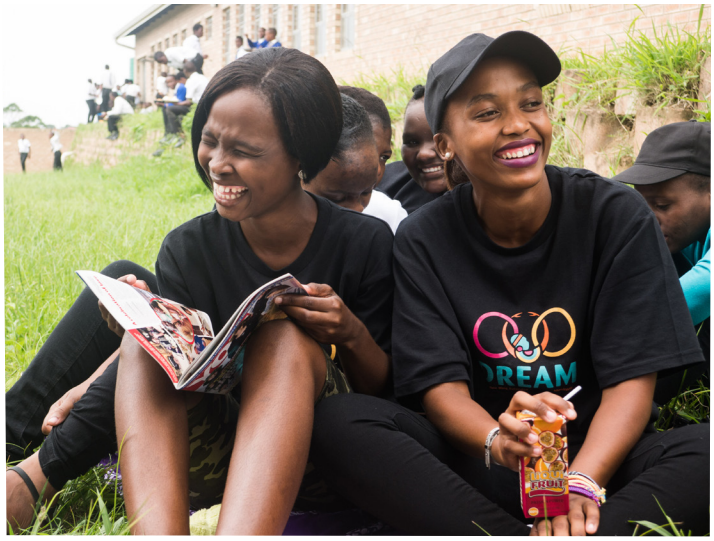
Since our inception, IPM has negotiated royalty-free licenses and an exclusive worldwide rights agreement from five leading pharmaceutical companies to develop nine promising ARVs as microbicides. These licenses ensure future IPM products will be affordable where the need is most urgent.

- **Conducting rigorous research studies**

IPM has worked in 11 countries in Africa, Europe and North America to conduct more than 45 clinical trials to date on a variety of products as well as 13 incidence studies and two acceptability studies, all of which continue to inform our work and the field's.

IPM Headquarters 8405 Colesville Road • Suite 600 • Silver Spring, MD 20910 USA **TEL:** +1-301-608-2221 **FAX:** +1-301-608-2241
IPM South Africa 63 Main Road • Paarl 7646, South Africa • P.O. Box 3460 **TEL:** +27-21-860-2300 **FAX:** +27-21-860-3208/1000
IPM Belgium Square de Meeûs 38/40, B1000 Brussels, Belgium

www.IPMglobal.org
@IPMicrobicides



■ Strengthening medical research capacity in Africa

IPM has collaborated with in-country partners and research staff to build and strengthen capacity at more than 15 research centers across sub-Saharan Africa. We trained more than 600 research center clinical staff, including community engagement teams on microbicide trial implementation. These staff are well-equipped to conduct high-quality HIV prevention and related clinical trials that contribute to the health of their communities.

■ Streamlining manufacturing processes

IPM led a state-of-the-art manufacturing facility to produce prototype gels and rings for early trials, resolving a manufacturing bottleneck and saving costs for more than 10 clinical studies. We transferred dapivirine ring production to an external manufacturer beginning with our Phase III studies to ensure cost-efficiencies for large-scale production, a process that will continue through post-trial manufacturing to keep costs as low as possible.

■ Advancing multipurpose products to address women's broad sexual and reproductive health needs

Because HIV and unintended pregnancy are major causes of serious health complications and death for women worldwide, IPM is developing a multipurpose technology: a three-month dapivirine-contraceptive ring designed to offer both HIV prevention and contraception. A Phase I trial began in 2017.

■ Developing the first combination ARV ring

IPM developed the first combination ARV vaginal ring to reach clinical trials, the dapivirine-maraviroc ring, and is exploring formulations using potent new ARVs. Combining ARVs with different mechanisms of action may provide greater protection against HIV than a single drug alone and reduce the chance of acquiring drug-resistant HIV.

What Does the Future Hold?

The first long-acting, self-initiated HIV prevention product for women potentially approved for public use

IPM is pursuing approvals from global and national regulatory authorities to license the product for use in countries where women face the highest risk for HIV. First approvals in Africa could come as soon as early 2019.

Access to products where the need is urgent

In parallel, IPM is collaborating with global, regional and national partners to determine how the dapivirine ring could best fit into prevention programs, and plan for its potential rollout to the women who would most benefit from it. In addition, two open-label extension studies are providing former Phase III participants with access to the dapivirine ring and will help answer critical questions about the product and its use while it is under regulatory reviews.

Cutting-edge pipeline and novel mechanisms of action

IPM is leveraging its innovative ring technology to develop a range of next-generation prevention products that advance the science of HIV prevention. These include a three-month dapivirine-only ring as well as combination rings that leverage the potency of different ARVs.

Realizing the life-saving potential of new products for women is within our reach.

From Promise to Product

As women have increasingly become the face of HIV over the past decade, IPM has remained true to its vision by pioneering critically needed microbicide research and development to fill a gap in women's HIV prevention needs.

IPM extends its deepest thanks to our partners around the world and to our generous donors, all of whom amplify our efforts to improve women's health. Realizing the life-saving potential of new products for women is within our reach. But only by continuing to unite scientific discovery with political will and financial commitment, will we meet women's urgent sexual and reproductive health needs globally.