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***Final Results of Open-label Study of IPM's Dapivirine Vaginal Ring Show Increased Use and Suggest Lower Infection Rates Compared to Earlier Phase III Study***

**Durban (13 June 2019)**—Final data from an open-label extension study of the monthly dapivirine ring show increased product use compared to a previous Phase III study. In addition, modeling data suggest that women's HIV-1 risk in the open-label study, known as DREAM, was reduced by 63%.

Developed by the nonprofit International Partnership for Microbicides (IPM), the ring is designed to provide women with a discreet and long-acting HIV prevention option. The vaginal ring, which women can insert themselves, slowly releases the antiretroviral (ARV) drug dapivirine over the course of a month and is currently under regulatory review.

Results from DREAM, announced today at the 9<sup>th</sup> South African AIDS Conference, showed an increase in ring use over its parent Phase III study, known as The Ring Study, with 95% of women in DREAM using the ring at least some of the time. Adherence is assessed by measuring residual levels of dapivirine in used rings.

The analyses also suggest that the overall HIV incidence rate among women in the DREAM study is 63% lower than would be expected without use of the dapivirine ring based on statistical modeling. This finding has limitations due to the lack of a placebo comparison group in the open-label study (meaning that all participants were using the active product).

Today's news builds on [Phase III results](#) from IPM's Ring Study, announced in 2016, which showed that the dapivirine ring reduced HIV risk by about 30% overall and was well-tolerated with long-term use.

"The DREAM results support the outcome we hoped to see—that when women knew that the dapivirine ring helped to lower HIV risk in the Phase III trials, they were more likely to use it and to potentially see higher levels of protection," said Dr. Zeda Rosenberg, founding chief executive officer of IPM. "Today's findings give us insight into how women might use the ring in the real world."

IPM extends its deep thanks to the women who participated in DREAM, and to their families and communities, for their dedication to finding new HIV prevention tools that women can use on their own terms.

Results from another open-label extension study of the ring, called HOPE, conducted by the US National Institutes of Health-funded Microbicide Trials Network (MTN), are expected this year. HOPE was a follow-on study to ASPIRE, a second Phase III trial of the ring that reported similar results to The Ring Study.

**About DREAM**

DREAM (Dapivirine Ring Extended Access and Monitoring/IPM 032) was an open-label extension study that provided the dapivirine ring to women who participated in the Phase III ring trial, The Ring Study,

and who tested HIV-negative, were not pregnant and were using an effective contraceptive method. DREAM collected additional safety data and information on how women used the ring once they were aware it was shown to reduce HIV risk in the Phase III study.

IPM led DREAM at six former Ring Study sites in South Africa and Uganda among 941 women ages 20-50. DREAM began in July 2016 and completed in January 2019. All participants were followed for approximately 12 months. All women received regular HIV testing and risk reduction counseling, condoms, testing and treatment for sexually transmitted infections, and adherence counseling.

### **Results: DREAM and comparison to The Ring Study**

- **Safety:** The ring was found to be well-tolerated in DREAM with a safety profile similar to The Ring Study.
- **Adherence:** Adherence to the ring was assessed by measuring residual dapivirine levels in used rings, which were returned at each study visit. Current methods are unable to determine the precise duration of ring use, but final data from DREAM show an increase in used rings that indicated at least some use (ranging from intermittent to consistent use), up from 83% in The Ring Study to 95% in DREAM.
- **Risk reduction:** DREAM data suggest a 63% reduction in HIV-1 risk using statistical modeling. From July 2016 to November 2018, an HIV-1 incidence of 1.6 percent was observed, compared to an incidence rate of 4.3% in a simulated placebo group, which was based on data from participants with similar characteristics in the placebo arm of The Ring Study. As noted, the lack of a contemporaneous placebo group in DREAM poses important limitations on its comparison to the placebo-controlled Ring Study, which should be considered when interpreting these results.

As previously announced in 2018, [interim data](#) from both open-label studies of the dapivirine ring, DREAM and HOPE, showed increased ring use and suggested increased HIV risk reduction compared to the Phase IIIs, by about 50% overall.

### **Advancing new options for women**

The dapivirine ring is currently under regulatory review by the European Medicines Agency (EMA) through the Article 58 procedure, which allows the EMA, in cooperation with the World Health Organization (WHO), to provide a scientific opinion on the ring's use in low- and middle-income countries. IPM also plans to submit applications to the South African Health Products Regulatory Authority (SAHPRA) and the US Food and Drug Administration (FDA) later this year.

Despite progress against the epidemic, women remain at alarmingly high risk for HIV, especially in sub-Saharan Africa where nearly 60% of adults living with HIV/AIDS are women. If approved, the ring could fill an important gap with the first long-acting HIV prevention method for women unable to use daily oral PrEP. Because no single approach will meet everyone's needs, a comprehensive range of prevention options is needed to control the epidemic—including condoms, daily PrEP, long-acting rings and other methods in development.

IPM is also developing a three-month dapivirine-only ring that could offer women a longer-acting prevention option and reduce annual costs, and a three-month dapivirine-contraceptive ring to simultaneously offer HIV prevention and contraception. Both products are in Phase I trials.

IPM holds an exclusive worldwide license for dapivirine from Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, designed to ensure that women in low-resource settings have affordable access to any dapivirine-based microbicide.

IPM's work is made possible through generous support from the Danish Ministry of Foreign Affairs, Flanders Department of Foreign Affairs, Irish Aid, the German Federal Ministry of Education and Research (BMBF) through the KfW Development Bank, the Ministry of Foreign Affairs of the Netherlands, UK aid from the British people, the American people through the United States Agency for International Development (USAID) in partnership with the US President's Emergency Plan for AIDS Relief (PEPFAR), and the Bill & Melinda Gates Foundation.

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**About the dapivirine ring:** The flexible silicone ring provides sustained-release of the ARV drug dapivirine locally to the site of potential infection during vaginal sex with minimal absorption elsewhere in the body. Women insert the product themselves and replace it every month.

**About IPM:** IPM is a nonprofit organization dedicated to developing new HIV prevention tools like the dapivirine ring and other sexual and reproductive health technologies for women, and making them available in developing countries. IPM has offices in South Africa, the United States and Belgium. Please visit [www.IPMglobal.org](http://www.IPMglobal.org).

**Editor's note:** Final DREAM results will be presented as an oral presentation, "Safety, Adherence And HIV-1 Seroconversion In DREAM—An Open-Label Dapivirine Vaginal Ring Trial" on **13 June at 16:00-17:30 in Hall 1** along with "Long-Term Follow-up of Seroconverters From Dapivirine Vaginal Ring Trials—The Ring Study and DREAM." Also visit our poster presentation #6, "Dapivirine Vaginal Ring reduces the risk of HIV-1 infection among Women in Africa."