Why Did IPM Develop the Dapivirine Ring?

• Available methods have not done enough to slow the epidemic among women
• Need for discreet products that women can use on their own terms
• No one product will solve the HIV epidemic
• Women need multiple prevention options that make sense for their lives
  • On-demand, daily, monthly or longer
  • Non-systemic or systemic
Monthly Dapivirine Ring: Overview

- Flexible silicone vaginal ring developed by IPM
- Woman-initiated
  - Self-inserted monthly
  - Discreet
  - Does not interfere with sex
- Slowly releases ARV dapivirine
  - Exclusive worldwide rights through Janssen Sciences Ireland UC
- Reduced HIV risk in Phase III trials: 35% in The Ring Study, 27% in ASPIRE
- Open-label extension studies saw increased adherence, suggested greater risk reduction
- First long-acting HIV prevention product
Regulatory Reviews
A Milestone: Positive EMA Opinion

In July 2020, the European Medicines Agency (EMA) adopted a positive scientific opinion for the ring’s use by cisgender women ages 18 and older in developing countries to reduce their HIV risk.

- Reviewed under **EMA Article 58**, in cooperation with the WHO, to facilitate access to essential medicines in developing countries using the same rigorous standards as for products intended for use in the European Union.
- Positive opinion **recognized by many national regulators in Africa** and can facilitate WHO prequalification, guidelines.
- The opinion is a **key step** on the path to making the ring available where it is urgently needed.
What Happens Next?

- Scientific opinion on use of a product in developing countries (via Article 58 procedure)
- Positive opinion adopted July 2020

European Medicines Agency (EMA) Art 58 Positive Opinion

World Health Organization (WHO)

WHO participates in EMA Article 58 procedure and facilitates WHO abbreviated prequalification (PQ) and Collaborative Registration Procedure (CRP)

IPM application for WHO abbreviated PQ

IPM request to WHO, NMRAs and SRA to use SRA CRP

IPM submits dossiers via CRP

African National Medicines Regulatory Authorities (NMRAs) approvals (includes SAHPRA)

Planned submission Q4 2020

Note: Timelines are estimates and subject to change
Planning for Access
Access Strategy

**Clinic/Public Hospital Access**
Drive ring awareness/education to encourage provider referrals to patients

**Government & Donor Support**
Include the ring in policy guidelines and funding decisions

**Operations & Logistics**
Deliver the ring to clinics/hospitals via approved channels and partnerships

**End-User Access**
Drive women's awareness, education and use of the ring
Additional Monthly Ring Research

- Phase IV post-authorization study among cisgender women ages 18-25 to better understand the ring’s efficacy
  - Assess efficacy in two age groups: 18-21 and >21-25
  - Collect data on potential ARV resistance as well as safety
  - Could also inform adherence support strategies

Additional research led by MTN in partnership with IPM:

REACH study: Adolescent girls and young women
- Safety and use of dapivirine ring and oral PrEP among 300 young women ages 16-21 in South Africa, Uganda, Zimbabwe; began Feb. 2019

DELIVER study: Pregnant women
- Safety and acceptability of ring and PrEP among 750 women in Malawi, South Africa, Uganda, Zimbabwe; began Feb. 2020

B-PROTECTED: Breastfeeding women
- Safety and acceptability of ring and PrEP in Africa planned for 2020
Follow-on Rings
Studies led by MTN in partnership with IPM

Building on monthly ring, longer-acting rings could:
• Increase convenience to women
• Lower annual costs

3-month dapivirine ring
• Phase I results expected by early 2021

3-month dapivirine-levonorgestrel ring
• HIV prevention and contraception
• First Phase I trial results: well-tolerated, encouraging drug levels seen in blood and vaginal fluid
• Second Phase I trial results expected by early 2021
A future where every woman has options to protect her health is a future where women will thrive.
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THANK YOU!