Dapivirine Vaginal Ring Development Programme Update

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International Partnership for Microbicides

14th February 2018
What we know about the ring…
Microbicide Vaginal Rings

• Long-acting: monthly or longer
  – Could support improved adherence
  – Thus better effectiveness

• Easy to use, comfortable
  – Flexible ring, can be self-inserted
  – Rarely felt by the user or male partner
  – High willingness-to-use
  – Little or no impact on sexual experience

• Suitable for developing countries
  – Relatively low manufacturing cost
  – Good safety and acceptability data

• Potential for drug combinations

Important potential new option for women
Phase III Results Summary

- IPM’s monthly dapivirine ring reduced HIV risk by approximately 30% overall
- Higher protection seen in women older than 21
- Higher efficacy seen with consistent use (as high as 75%)
- More research needed to understand prevention needs of younger women
- The dapivirine ring is safe
Regulatory Pathway for Dapivirine Vaginal Ring
Path to Approval

Why do we need regulatory approval of medicines?

“EMA, FDA, NDA, MCC, SAHPRA, PMPB, PPB, TFDA, MCAZ” 😊

Harmonisation – ZAZIBONA, EACMH
But why does it take so long?

For the dapivirine ring, IPM has organised 13 years of data and findings from nearly 250 studies into each application

260,000 pdf pages
1,200 files
69,000 links
4.4 terrabytes
>10 hours to upload

Approval pathway for new HIV prevention drug can be more complex than for a drug already approved for treatment (e.g., oral Truvada)
Regulatory Path: Overview

European Medicines Agency (EMA)
- Scientific opinion on a product's use in developing countries (via Article 58 procedure)
- Submitted June 2017; currently under review

World Health Organization (WHO)

African National Regulatory Authorities
- Following WHO PQ, first submissions to Kenya, Malawi, Rwanda, Tanzania, Uganda, Zambia, Zimbabwe
- Target submission Q2 2018

South African Medicines Control Council (MCC)

US Food and Drug Administration (FDA)
- Target submission Q4 2018

Why WHO Prequalification?
- Process to evaluate whether a drug meets global standards for quality, safety and efficacy
- Most African regulatory agencies use WHO prequalification to determine which new products to approve
Regulatory Timeline

- 2016: Open-label extension study: DREAM
- 2017: Open-label extension study: HOPE
- 2018: African adolescents safety study: REACH
- 2019: Safety studies in pregnant and breastfeeding women
- 2020: African NRAs (submission & approval)

Supporting safety and PK studies

EMA Article 58

WHO PQ

US FDA

S. Afr. MCC (SAHPRA)
Some Access Activities
Dapiring brand name selection including trademark clearance search

- Focus groups with 300+ women in all 4 Phase III countries
- J&J trademark clearance search completed
- Lead and backup candidate names identified:
  - Lead name: DAPIRING; Back up name:
  - Process underway to trademark the names in all target African countries and US

Package design & market testing for final package selection
Access Advisory Committee Members
## Market Introduction/Launch Readiness Priority Areas 2017-2019

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