Years Ahead in HIV Prevention Research

Time to Market

Prevention Product | 2022 (Q1–Q4) | 2023 (Q1–Q4) | 2024 (Q1–Q4) | 2025 (Q1–Q4) | 2026 (Q1–Q4) | 2027 (Q1–Q4) | 2028 (Q1–Q4)

Vaginal Ring

Dapivirine
monthly

- Multiple regulatory approvals
- Multiple implementation science projects
- WHO guidelines
- Selected Global Fund procurement and programs

- Demonstrated modest efficacy
- Unclear demand & limited initial supply
- Initial price ~$180 per year
- Oct 2023: A memorandum of understanding has been reached on a product license with Kiara
- 3-monthly ring is currently in development and could be submitted to regulators in 2025
- Opportunity to build market and platforms for vaginal rings

Long-Acting Injectables

Cabotegravir
One intramuscular injection (3ml) every 2 months

- Multiple regulatory approvals
- Multiple implementation science projects
- WHO guidelines
- Selected PEPFAR and Global Fund procurement and programs

- Demonstrated high efficacy
- Unclear demand & limited initial supply
- Initial LMIC price ~$240/yr; in 2024 ~$170/yr
- March 2023: MPP & ViiV licensed to 3 generics with likely submission to regulators by 2027
- 4-monthly formulation is currently in development, but the regulatory timeline is unclear
- Opportunity to build market and platforms for injectables

Lenacapavir
Two subcutaneous injections (1.5ml each) every 6 months

- Phase 3: PURPOSE 1 & 2
- Phase 2: PURPOSE 3, 4, 5
- Possible regulatory approvals
- Possible product introduction

Oral PrEP

F/TAF
daily

- Phase 3: part of PURPOSE 1
- Possible regulatory approvals

MK-8527
monthly

- Phase 2a: MK-8527-07
- Possible Phase 3
  Possible Go/No-Go Decision for Phase 3 in Q1 2025

Dual Prevention Pill

Co-formulated TDF/FTC and ethinyl estradiol/ levonorgestrel oral contraceptive pill
daily

- Pilot bioequivalence (BE) study
- Pivotal BE
- Possible regulatory approvals
- Possible product introduction
- Acceptability Study: HPTN 104

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