Years Ahead in HIV Prevention Research

Time to Market

Prevention Product | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028

Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

Vaginal Ring

Dapivirine
monthly

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

- Demonstrated high efficacy
- Unclear demand & limited initial supply
- Initial LMIC price ~$240/yr; in 2024 ~$180/yr; from 2025, ~$160/yr
- March 2023: MPP & ViiV licensed to 3 generics with likely submission to regulators by 2027
- 4-monthly formulation is currently in development, with submission for regulatory approval expected in early 2026
- Opportunity to build market and platforms for injectables

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

- Phase 3: PURPOSE 1 & 2
  - Initial results showed no infections in the LEN arm for PURPOSE 1 and a 96% reduction in HIV infections compared to background HIV incidence for PURPOSE 2.
- Phase 2: PURPOSE 3, 4, 5
- Possible regulatory approvals
- Possible product introduction

- Demonstrated very high efficacy
- Dec 2024: Global Fund & PEPFAR commit to reaching 2m users in first three years
- Initial LMIC price unclear
- Oct 2024: Gilead licensed to 6 generics with likely submission to regulators by 2027
- Once-yearly formulation is currently in development, with submission for regulatory approval expected in 2027
- Opportunity to understand if market can bear two injectables

Oral PrEP

F/TAF
daily

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

MK-8527
monthly

- Phase 2a: MK-8527-07
- Phase 3
  Possible trial launch in Q3 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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