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
- WHO Guidelines
- Multiple implementation science projects
- Selected Global Fund procurement and programs

- Demonstrated modest efficacy
- Unclear demand and limited initial supply
- Initial price ~$180/yr; 2025: ~$71/yr
- Oct 2023: A memorandum of understanding reached on a product license with Kiara
- 3-monthly ring currently under review by EMA; if approved, is expected to become available in 2027 and replace one-monthly ring
- 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 Global Fund and PEPFAR procurement and programs

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

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

- Phase 3: PURPOSE 1 & 2
- Initial results showed no infections in the LEN arm for PURPOSE 1and a 96% reduction in HIV infections compared to background HIV incidence for PURPOSE 2
- Phase 2: PURPOSE 3, 4, 5
- Approved by US FDA, EMA, SAPHRA; others pending
- WHO Guidelines
- Selected GF and PEPFAR procurement and programs

- Demonstrated very high efficacy
- Dec 2024: Global Fund & PEPFAR commit to reaching 2 million users in first 3 yrs; updated to 3 million in Apr 2026
- Initial LMIC price unclear; 2027: generic price of ~$55 for loading dose + injections and ~$40 for ongoing use
- Oct 2024: Gilead licensed to 6 generics with likely regulatory submission by 2027
- Once-yearly formulation currently in development, with regulatory submission expected in 2027
- Opportunity to understand if market can bear 2 injectables

Oral PrEP

F/TAF
daily

- Phase 3: part of PURPOSE 1
- Regulatory pathway unclear

Lenacapavir
weekly

- Review by US FDA

MK-8527/alimatravir
monthly

- Phase 2a: MK-8527-07
- Phase 3: EXPrESSIVE-10 launched November 2025 and EXPrESSIVE-11 launched August 2025

- Jul 2026: Merck licensed to 7 generics as Phase 3 trials continue

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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July 2026