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		Multiple implementation science projects				
	WHO Guidelines		Selected Global Fund procurement and programs				
Long-Acting Injectables							
Cabotegravir One intramuscular injection (3ml) every 2 months	Multiple regulatory approvals		Multiple implementation science projects				
	WHO Guidelines		Selected Global Fund and PEPFAR procurement and programs				
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	Approved by US FDA, EMA, SAPHRA; others pending	Selected GF and PEPFAR procurement and programs			
		Phase 2: PURPOSE 3, 4, 5	WHO Guidelines				
Oral PrEP							
F/TAF daily	Phase 3: part of PURPOSE 1		Regulatory pathway unclear				
Lenacapavir weekly					Review by US FDA		
Alimatravir monthly	Phase 2a: MK-8527-07		Phase 3: EXPrESSIVE-10 launched November 2025 and EXPrESSIVE-11 launched August 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		

- 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

- 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

- 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 LEN to 6 generics
- Nov 2026: First generic LEN approved by FDA
- Once-yearly formulation currently in development, with regulatory submission expected in 2027
- Opportunity to understand if market can bear 2 injectables

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

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