



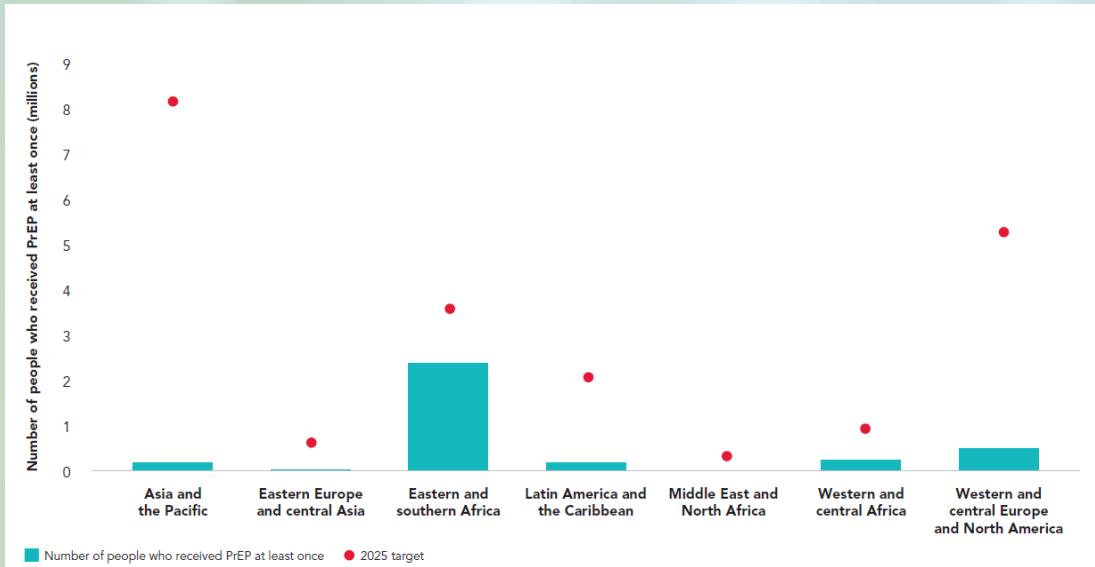
LONG-ACTING PREP: RE-ENERGIZING THE HIV PREVENTION LANDSCAPE

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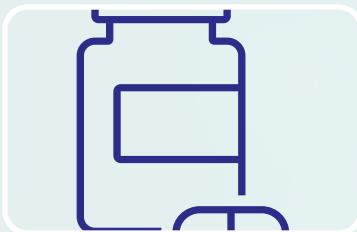
The global reach of PrEP



- HIV (2023)
 - 20.8 million
 - 1.3 million new infections
 - 630K AIDS-related deaths
- PrEP
 - 3.5 million used PrEP at least once by 2023
 - Need 21.2 million using PrEP at least once (e.g. PrEP for 10 million)

PrEP milestones

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2012

TDF/FTC* for
PrEP & WHO
PrEP Guidelines
released

2019

TAF/FTC for
PrEP in certain
populations

2021

Dapivirine ring
for PrEP

2021

Cabotegravir for
injectable PrEP

Current state of LA-PrEP

Dapivirine Ring

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RING (n=1959)

- DPV: 4.1 infections/100 PY (n=77)
- PBO: 6.1 infections/100 PY (n=56)
- 31% lower incidence of HIV



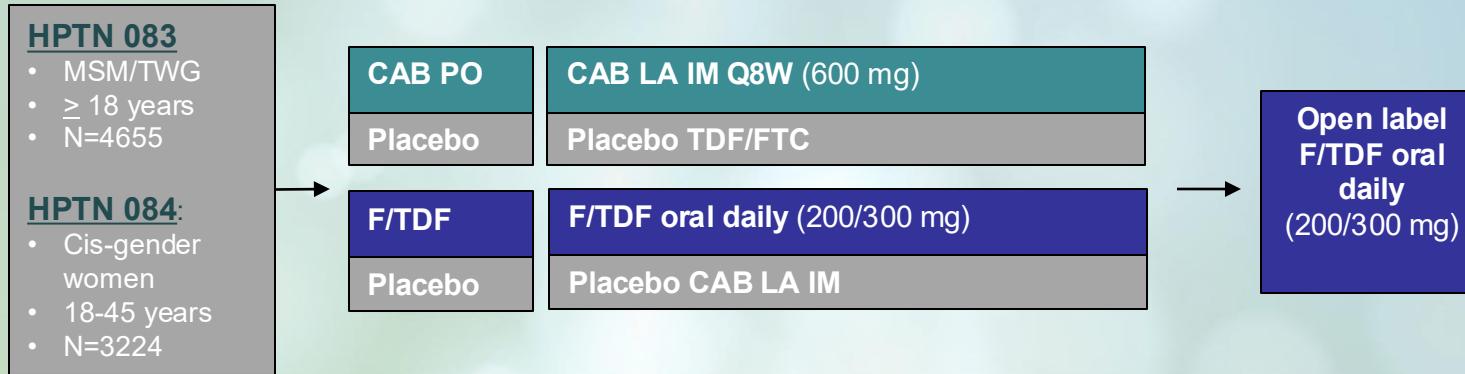
ASPIRE (n=2629)

- DPV: 3.3 infections/100 PY (n=71)
- PBO: 4.5 infections/100 PY (n=97)
- 37% lower incidence of HIV

Current state of LA-PrEP

Long-acting cabotegravir

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- HPTN 083:** 69% reduction in HIV incidence (12 vs. 39 infections)
- HPTN 084:** 90% reduction in HIV incidence (3 vs. 36 infections)

On the horizon

Drugs with new indications: lenacapavir

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PURPOSE-1

- Cis-gender female
- 16-25 years
- N=5338

LEN SC every 26 weeks (927 mg, n=2134)

+ Placebo F/TXF

F/TAF oral daily (200 mg/25 mg, n=2136)

+ Placebo SC LEN

F/TDF oral daily (200 mg/300 mg, n=1068)

+ Placebo SC LEN

BACKGROUND HIV INCIDENCE

- **Background:** 2.41 infections/100PY
- **F/TAF:** 2.02 infections/100PY
- **F/TDF:** 1.69 infections/100PY
- **LEN SC:** 0 infections/100PY

PURPOSE-2

- Cis-gender /BMSM, TGW, TGM, GNB
- ≥ 16 years
- N=3265

LEN SC every 26 weeks (927 mg, n=2179)

+ Placebo F/TXF

F/TDF oral daily (200 mg/300 mg, n=1086)

+ Placebo SC LEN

BACKGROUND HIV INCIDENCE

- **Background:** 2 infections/100PY
- **F/TDF:** 0.93 infections/100PY
- **LEN SC:** 0.10 infections/100PY

LA-PrEP innovations

New agents: MK-8527

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Completed ⓘ

Safety and Pharmacokinetic Study of Oral MK-8527 QM in Participants at Low-Risk for HIV-1 Infection (MK-8527-007)

ClinicalTrials.gov ID ⓘ NCT06045507

Sponsor ⓘ Merck Sharp & Dohme LLC

Information provided by ⓘ Merck Sharp & Dohme LLC (Responsible Party)

Last Update Posted ⓘ 2025-03-13

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Study Overview

Brief Summary

This double-blind, placebo-controlled study is designed to assess the safety, tolerability, and pharmacokinetics of oral MK-8527 taken once monthly (QM) in participants at low risk for human immunodeficiency virus Type 1 (HIV-1) infection.

Official Title

A Phase 2a, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Oral MK-8527 Once Monthly in Participants at Low-Risk for HIV-1 Infection

Conditions ⓘ

[HIV](#) [HIV Pre-exposure Prophylaxis](#)

Intervention / Treatment ⓘ

Study Start (Actual) ⓘ 2023-11-08

Primary Completion (Actual) ⓘ 2024-12-12

Study Completion (Actual) ⓘ 2025-02-12

Enrollment (Actual) ⓘ

Study Type ⓘ

- Novel nucleoside reverse transcriptase translocation inhibitor (NRTI)
- Once monthly, oral
- Phase II study
 - Single dose/ascending doses in adults aged 18-55 without HIV

<https://clinicaltrials.gov/study/NCT06045507>



More LA-PrEP innovations

Multipurpose prevention technology

TFV + LNG
DPV + LNG



Less frequent administration

3 month DPV ring



Less frequent administration

ULA cabotegravir



Less frequent administration

Annual LEN



Benefits, unknowns, and the architecture of choice

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- Collateral benefits
 - Reduction in stigma
- The not-completely-knowns
 - Resistance, implementation, access/equity
- Optimal use of these emerging LA-PrEP tools
 - Education, preferences, and shared decision making



Looking forward



- PrEP remains essential to ending the HIV epidemic
- The more tools/technologies, the better
- Continue to set goals
 - Everyone who needs PrEP has access to it
 - Everyone who wants PrEP is offered choices