

## DISEASE BURDEN

In 2024, 40.8 million people globally were living with HIV, 1.3 million people became newly infected, and 630,000 people died of HIV, most of which occurred in LMICs. Despite advances in treatment leading to a reduction in onward transmissions, reductions in HIV incidence remain off track to meet global targets, with HIV incidence even raising in some regions. As such, HIV prevention remains an essential component of the HIV response, with PrEP and PEP being central tools for this objective.



Priority

SEPT. 2025



## CLINICAL RELEVANCE

Daily oral PrEP, although very effective, requires persistent adherence, fueling demand for long-acting PrEP options. MK-8527, a once-monthly oral NRTTI, could improve adherence; Two ongoing pivotal Phase 3 trials, EXPrESSIVE-10 and EXPrESSIVE-11 compare monthly MK-8527 to daily oral PrEP, with HIV incidence over 1–2 years as the primary endpoint and safety/tolerability as key outcomes. Trials will complete in 2027.



## SERVICE DELIVERY ENABLERS

MK-8527's oral, long-acting format is well-suited for decentralized, differentiated, multi-month, task-shared, and user-centred delivery models, making it a strong candidate for integration into both public and private health systems. The use of rapid HIV tests (including self-tests) for initiation of oral monthly PrEP could support initiation. Its investigated use as a single-pill PEP option with rapid activity onset could also allow for simplified service delivery.



## MANUFACTURING

The manufacturing process for tablets is not disclosed. Since this is an oral formulation, a sterile facility will not be required. There will be no complex delivery device required. No information related to excipients, occupational exposure limit or shelf life is currently available.

## INTELLECTUAL PROPERTY LANDSCAPE

Primary patents on MK-8527, with an expected expiry in 2035, have been granted to MSD in at least 40 LMICs, including key countries of manufacture such as India, China, South Africa and Brazil, with applications pending in an additional 9 LMICs. Secondary patent filings are anticipated.



## MK-8527



HIV  
PREVENTION

MSD

## REGULATORY

MK-8527 is an investigational drug currently in clinical phase. Since the product is an oral formulation of a small molecule, generics would be required to establish PK based bioequivalence study. Being a long-acting solid oral formulation, BCS-based biowaivers are not applicable.



## MARKET

Despite funding cuts and the need for governments to prioritize HIV treatment, PrEP rollout had reached 8 million initiations by the end of 2024 and continues to grow, largely building on the promise of long-acting options and choice. As an additional potentially cheap and easy to deliver long-acting PrEP option, MK-8527 could be a candidate for future scale up and thereby contribute to meaningfully reduce HIV incidence towards global targets.

