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Editorial

Lenacapavir: a long-acting human immunodeficiency virus prevention strategy with the potential to transform global human immunodeficiency virus control

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Human immunodeficiency virus (HIV) has become one of the greatest global public health issues in existence, currently affecting an estimated 39 million individuals worldwide in 2024, and there are over 1.3 million new infections each year.[1] HIV is a type of retrovirus that specifically infects CD4+ T cells, resulting in progressively compromised immune function, and if untreated, will eventually develop into acquired immunodeficiency syndrome (AIDS). While early infection with HIV can cause nonspecific symptoms such as fever, rash, swollen lymph nodes, and fatigue; the chronic stage is defined by opportunistic infections and malignancies.[2] Although there has been great advancement in both diagnostic methods and treatments for HIV; persistent poor adherence to daily pre-exposure prophylaxis (PrEP) continues to hinder the potential of preventative measures, particularly within the population of young women and men who have sex with men (MSM).

Lenacapavir (LEN), is a first-in-class long-acting capsid inhibitor representing the next generation of HIV prevention methods. LEN functions by binding to the HIV-1 capsid protein causing disruptions to various aspects of the HIV-1 virus lifecycle including; capsid assembly, disassembly, nuclear entry, and reverse transcription.[3] The administration of LEN via a subcutaneous injection once every 6 months provides sustained plasma concentrations greater than the concentration required for protection against HIV infection, providing a practical and effective alternative to the daily oral regimen of tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) used in oral PrEP.[4]

Significant reductions in HIV acquisition were found between participants receiving LEN and those receiving TDF/FTC in oral form daily in the recent findings of the PURPOSE 1 and PURPOSE 2 Phase III clinical trial studies.[5] The long-acting properties of LEN are designed to address adherence challenges, reduce the stigma associated with pill-taking, and simplify the delivery models to high-burden populations, all of which could significantly increase the use of this method within these populations. Table 1 summarizes key differences between LEN and existing oral PrEP regimens.

The integration of LEN into public health systems has great potential to significantly lower the incidence of HIV, particularly in Sub-Saharan Africa, Southeast Asia, and other at-risk populations world-wide. Its success depends on equitable access, pricing, and training of healthcare workers. Implementation research is urgently needed to evaluate cost-effectiveness, cold-chain management feasibility, and community acceptability.

Table 1: Comparative characteristics of oral PrEP and Lenacapavir for HIV prevention.

Feature	Oral PrEP (TDF/FTC)	LEN
Drug class	NRTI combination	HIV capsid inhibitor
Dosing frequency	Daily oral	Subcutaneous injection every 6 months
Primary barrier	Adherence, stigma	Cost, cold-chain logistics
Efficacy (trial-based)	>90% with perfect adherence	>95% in phase III interim data[5]
Target population benefit	General high-risk groups	High-risk groups with adherence challenges

LEN's mechanism of action, prolonged protection and improved compliance with treatment are major advancements in the prevention of HIV. The strategic inclusion of LEN in national and international HIV programs can lead to an accelerated pace to meet the UNAIDS 95-95-95 target and may also shift the trajectory of the HIV epidemic.

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