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#### **DISEASE BURDEN**

In 2023, 39.9 million people globally were living with HIV, 1.3 million people became newly infected, and 630,000 people died

**LENACAPAVIR** 

HIV

PrEP

Gilead

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**CLINICAL RELEVANCE** 

medicines patent pool

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Lenacapavir, a novel long-acting capsid inhibitor for HIV prevention, is developed as a twice-yearly subcutaneous injection following an initial oral loading. Phase III trials (PURPOSE 1 & 2) showed high effectiveness with mild injection site reactions. Lenacapavir PrEP injections are also safe and effective in adolescents, expanding the product's potential impact. New intramuscular formulations with potential for a once-yearly administration for HIV prevention are investigated. A future shift to yearly dosing could improve adherence and accessibility, especially in resource-limited settings.

## SERVICE DELIVERY ENABLERS

Lenacapavir for PrEP does not require a companion drug. While long-acting injectable lenacapavir may warrant higher adherence, health system requirements for delivery might be higher compared to once-daily oral PrEP options that can be handed to clients for several months supply.

## MANUFACTURING

Assuming the formulation is the same as the approved treatment: a spray-drying process is adopted for mandatory loading dose oral formulation. Injectable product is a standard solution, terminally sterilised. Standard excipients are used. The injectable formulation contains a specialised syringe along with vials. Shelf life is two years at room temperature for the tablets and the injectable product.

## INTELLECTUAL PROPERTY LANDSCAPE

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# REGULATORY

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Lenacapavir for PrEP is not approved by regulatory authorities yet. Submissions for approval were filed to EMA and USFDA. Bioequivalence studies are necessary for oral solid formulations. Biowaivers will not be an option for oral solid formulations. There is a possibility of biowaiver for the injectable product.

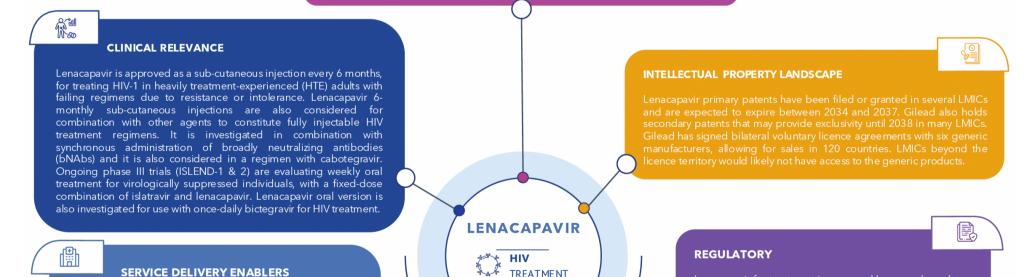
## MARKET

Gilead has indicated that it will prioritise registration in 18 countries among those covered in the bilateral licensing agreements. lenacapavir at "no profit" until generic versions of lenacapavir are available. No price is announced yet.

EMA: The European Medicines Agency; HIV: Human immunodeficiency virus; LMICs: low-income, lower middle-income and upper middle-income countries as per World Bank classification; PrEP: Pre-Exposure Prophylaxis; USFDA: The United States Food and Drug Administration

## **DISEASE BURDEN**

In 2023, 39.9 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.



TREATMENT

Gilead

#### SERVICE DELIVERY ENABLERS

Lenacapavir's possible companion drugs for a fully long-acting regimen are still under study. While long-acting injectable lenacapavir may have advantages in terms of adherence, health system requirements for delivery might be higher compared to once-daily oral treatment options such as TLD that can be handed to people needing the treatment with a multi-month dispensing. If successful, the oral weekly lenacapavir and islatravir candidate could support decentralised care while offering a valuable option for treatment.



## MANUFACTURING

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## MARKET

While lenacapavir is currently approved for HIV treatment by some major regulatory authorities for HTE adults, it is not yet registered - and is therefore not available- in LMICs. Gilead signed royalty-free voluntary licensing agreements with six generic manufacturers to increase access to lenacapavir for HIV treatment in 120 countries. acting companion injectable allowing for a fully injectable regimen

HIV: Human immunodeficiency virus; HTE: heavily treatment-experienced; LMICs: low-income, lower middle-income and upper middle-income countries as per World Bank classification; TLD: tenofovir, lamivudine and dolutegravir