

Accelerating Global Access to Lenacapavir

Scientific insight, at-risk manufacturing and coordinated partnerships

This fact sheet is for informational use only and is not intended for promotional use. Full Prescribing Information for lenacapavir, including important warnings, is available at [Gilead.com](https://www.gilead.com).

SCIENCE CONFIRMS POTENTIAL

Pivotal Phase 3 Results SEPTEMBER 12, 2024

Gilead announces results from pivotal clinical trial investigating the efficacy and safety of lenacapavir.

ACTING BEFORE CERTAINTY

Six voluntary licensing agreements signed OCTOBER 2, 2024

Prior to any global regulatory submission or confirmed demand, six royalty-free voluntary licensing agreements enable the production and supply of generic lenacapavir to 120 high incidence, resource limited countries.

FAST-TRACKED FOR IMPACT

Priority U.S. FDA review FEBRUARY 18, 2025

Twice-yearly lenacapavir becomes one step closer to reaching patients.

REGULATORY SUCCESS & ACCESS COMMITMENTS

A historic breakthrough JUNE 18, 2025

In a moment nearly 20 years in the making, U.S. FDA approves this novel use for lenacapavir.

FROM MANUFACTURING TO DELIVERY

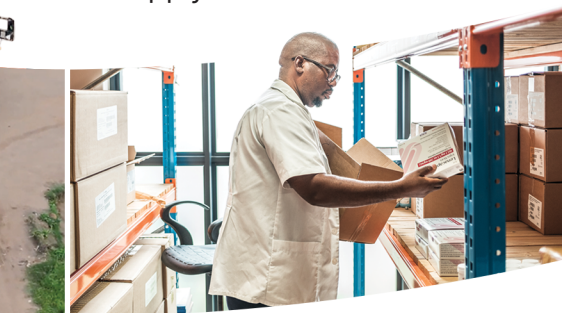
Lenacapavir arrives in sub-Saharan Africa NOVEMBER 18, 2025

First deliveries of lenacapavir arrive in sub-Saharan Africa just 5 months after U.S. FDA approval – the first time this type of breakthrough medicine has reached LLMICs and the U.S. the same year of approval.

TRANSITION TO SUSTAINABLE SCALE

Access of lenacapavir designed to evolve TODAY

- Gilead continues to provide bridge supply through the Global Fund and PEPFAR to support early access.
- Some generic manufacturers prepare to begin supply as early as 2027 – one year ahead of initial timelines.
- The pathway to high-quality, low-cost versions of lenacapavir is in sight as generic production scales to supply LLMICs.



Scaling up manufacturing capacity, at-risk

2024, IN PARALLEL

Investments into manufacturing capacity — including production of the Active Pharmaceutical Ingredient — begin at-risk to ensure sufficient supply if approved.

Rapid technology transfers to partners OCTOBER 2024

Generic manufacturers are empowered to file early, build manufacturing readiness and prepare large-scale supply.

Preparing supply for urgent low-and-lower-middle-income countries (LLMICs) access EARLY 2025

Manufacturing and production capacity continues to scale, including LLMIC-specific solutions for distribution and storage needs.

Coordinated partnership pathway JULY 9, 2025

Gilead, the Global Fund and PEPFAR coordinate strategic partnership to accelerate access to lenacapavir in LLMICs.

Bridging to sustainable access

Lenacapavir is made available at no profit for up to three million people over three years in LLMICs through the Global Fund and PEPFAR. This commitment ensures access during the interim period when Gilead is the sole supplier of lenacapavir.