EMBARGOED UNTIL 7:00AM ET, WEDNESDAY, SEPTEMBER 24, 2025

Gates Foundation Partners With Indian Manufacturer to Drive Down Cost of, Accelerate Access to Groundbreaking HIV Prevention Tool

New partnership will join others to expand access to generic lenacapavir for millions more people at risk of HIV in high-burden countries—bringing the world closer to ending the epidemic

NEW YORK (September 24, 2025) – Millions more people at risk of HIV in low- and middle-income countries (LMICs) will have access to a powerful new prevention option: a low-cost, generic version of **lenacapavir**, the world's first twice-yearly injectable pre-exposure prophylaxis (PrEP).

A new partnership announced today between the Gates Foundation and Indian manufacturer **Hetero Labs** (Hetero)—supported by upfront funding and volume guarantees—will enable the company to manufacture generic lenacapavir at roughly **\$40** per patient per year (after a short pre-treatment oral regimen), a price point designed to make the breakthrough treatment affordable for national health systems.

"Hetero is pleased to partner with the Gates Foundation to create a pathway for the sustainable and affordable supply of lenacapavir," said Dr. Vamsi Krishna, managing director of Hetero Group of Companies. "This collaboration reflects our commitment to ensuring access to innovative HIV medicines for patients in India and other low- and middle-income countries."

In a parallel move today, Unitaid, the Clinton Health Access Initiative (CHAI), and Wits RHI <u>announced</u> new commitments with Dr. Reddy's Laboratories Ltd. (DRL), another Indian manufacturer, reinforcing efforts to build a competitive generics ecosystem. The accelerated development of a large-scale generic supply of lenacapavir, which is anticipated as early as 2027 pending regulatory approval, will reduce the time between initial doses and provide wider access to the drug. This move could potentially transform the fight against HIV and help end the epidemic faster and more equitably.

The new collaborations complement <u>agreements</u> already in place between the Global Fund to Fight AIDS, Tuberculosis and Malaria; Gilead Sciences; and the U.S. State Department through PEPFAR, and supported by the Children's Investment Fund Foundation (CIFF), to roll out the initial supply of lenacapavir in LMICs, potentially reaching countries as early as the end of 2025.

A New Era for HIV Prevention

Lenacapavir for PrEP—approved by the <u>U.S. FDA</u> in June and the <u>European Commission</u> in August—offers six months of protection with a single injection, adding a powerful new prevention option for communities underserved by existing methods. Public health experts see it as a transformative option

for people who face barriers to daily oral PrEP, including <u>stigma</u>, adherence challenges, and inconsistent access to medication.

Despite global progress driving down HIV rates and AIDS-related deaths since 2000, **1.3 million people** acquired HIV in 2024, and only 18% of people who could benefit from PrEP currently have access. Modeling suggests that the introduction of lenacapavir has the potential to prevent significant numbers of HIV infections. In fact, one study showed that scaling up access to affordable lenacapavir to just 4% of the population in high-burden countries could prevent up to 20% of new infections. That potential drives the urgency of this investment.

Reducing the Burden of HIV/AIDS

As part of its broader commitment to ending deadly infectious diseases, the foundation has made more than \$80 million in catalytic investments to accelerate market readiness, scale delivery, and shorten the timeline for generic entry of lenacapavir.

"Scientific advances like lenacapavir can help us end the HIV epidemic—if they are made accessible to people who can benefit from them the most," said Trevor Mundel, president of global health at the Gates Foundation. "We are committed to ensuring that those at highest risk, who can least afford it, aren't left behind."

Today's announcement reflects the foundation's work with governments, communities, partners, and programs like the Global Fund and PEPFAR to ensure that **regulatory approvals**, **delivery systems**, **and community-led approaches** are in place to speed delivery of scientific breakthroughs to the people who often wait the longest.

This latest agreement builds on the foundation's long-standing support of the Global Fund, which has helped cut global HIV rates by 82% in countries where it invests. Earlier this week, Chair Bill Gates announced the foundation's \$912 million pledge to the Global Fund's 2026-2028 replenishment fundraising campaign, which aims to save 23 million lives from HIV, malaria, and tuberculosis between 2027 and 2029. The new agreements with Hetero and DRL will help the Global Fund increase impact by reducing costs at scale.

Building a Generics Ecosystem

In 2024, Gilead Sciences granted royalty-free licenses for lenacapavir production to six generic manufacturers for 120 low- and middle-income countries. Following regulatory approvals, generic lenacapavir will flow through national HIV programs and public procurement channels such as the Global Fund. The Hetero agreement also includes an affordable supply of the active pharmaceutical ingredient (API), enabling other generic manufacturers to scale quickly and efficiently.

"The deals announced today on generics are a major step forward in ending the HIV epidemic," said Kate Hampton, CEO of the Children's Investment Fund Foundation. "They build on full value-chain investments by CIFF and others to foster a competitive market so that access to lenacapavir is affordable and reliable for all those who need it."

Earlier this year, Gates made a <u>historic announcement</u> that he would give away virtually all of his wealth to the foundation to accelerate progress on saving and improving lives. He also announced the foundation would spend \$200 billion over the next 20 years, working with its partners to make as much progress as possible toward three primary goals: end preventable deaths of moms and babies; ensure the next generation grows up without having to suffer from deadly infectious diseases; and lift millions of people out of poverty, putting them on a path to prosperity. At the end of the 20-year period, the foundation will sunset its operations.

About the Gates Foundation

Guided by the belief that every life has equal value, the Gates Foundation works to help all people lead healthy, productive lives. In developing countries, we work with partners to create impactful solutions so that people can take charge of their futures and achieve their full potential. In the United States, we aim to ensure that everyone—especially those with the fewest resources—has access to the opportunities needed to succeed in school and life. Based in Seattle, Washington, the foundation is led by CEO Mark Suzman, under the direction of Bill Gates and our governing board.

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