

Global Fund, PEPFAR Announce Coordinated Effort to Reach 2 Million People with Lenacapavir for PrEP to Significantly Reduce Global HIV Infections

The coordinated effort aims to rapidly provide affordable and equitable access to twice-yearly PrEP.

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The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) and the United States President's Emergency Plan for AIDS Relief (PEPFAR) have joined forces with the Children's Investment Fund Foundation (CIFF) and the Bill & Melinda Gates Foundation (BMGF) to announce today [December 17] a coordinated effort that will rapidly provide affordable and equitable access to twice-yearly injectable lenacapavir for HIV pre-exposure prophylaxis (PrEP) contingent upon regulatory approval from the U.S. Food and Drug Administration, relevant national pharmaceutical regulators, and a recommendation from the World Health Organization (WHO).

The Global Fund and PEPFAR are aiming to secure sustainable arrangements for countries to access this new, potentially game-changing HIV prevention innovation – backed by a significant commitment from CIFF, and with support from BMGF – that would enable access to lenacapavir for at least 2 million people over three years in countries supported by PEPFAR and the Global Fund.

Gilead Sciences' lenacapavir is already approved in multiple countries to treat adults with multidrug-resistant HIV in combination with other antiretroviral drugs. Recent and highly promising [clinical trial results](#) show its potential in preventing new HIV infections as well. If rolled out at scale alongside other HIV prevention tools, including daily oral antiretroviral medications already approved for PrEP, lenacapavir has the potential to accelerate progress toward the 2030 Sustainable Development Goal 3 HIV target of ending HIV/AIDS as a public health threat, as well as ensuring a sustainable HIV response beyond 2030.

In October 2024, [Gilead announced](#) that it had signed non-exclusive, royalty-free voluntary licensing with six pharmaceutical companies to manufacture and supply high-quality, low-cost

versions of lenacapavir for HIV prevention for 120 primarily low- and lower-middle-income countries.

“At the Global Fund, we are incredibly excited by the promise of lenacapavir and its potential to help us achieve a further significant reduction in new infections among individuals at high risk of acquiring HIV,” said Peter Sands, Executive Director of the Global Fund. “As part of this coordinated effort, the Global Fund, PEPFAR, CIFF, and BMGF will work with Gilead and the voluntary licensing manufacturers to accelerate affordable and equitable access, so that more people can benefit from this powerful innovation from day one.”

“We cannot reach a sustainable HIV response without rapidly reducing the 1.3 million new HIV infections that occur worldwide every year,” said Ambassador Dr. John Nkengasong, U.S. Global AIDS Coordinator and Senior Bureau Official for Global Health Security and Diplomacy at the U.S. Department of State. “Lenacapavir offers a potentially tremendous opportunity to transform the impact of HIV programs to ensure adolescent girls and young women, key populations, and others who could benefit have access to highly effective HIV prevention, testing and treatment services and to end HIV/AIDS as a public health threat by 2030.”

Sir Chris Hohn, CIFF’s Founder and Chair said, “We must urgently break the cycle of HIV transmission and get back on track to achieve the 2030 goals. Testing and prevention are vital, where innovations like lenacapavir can profoundly impact the lives of millions. It will be a travesty if the communities who need it most don’t have access. That is why this collaboration is so essential to ensure that lenacapavir is available as soon as possible for those who need it the most.”

“Implementation of affordable lenacapavir at scale, alongside other HIV prevention interventions, has the potential to catalyze improved sustainability of the HIV response, with countries and communities having choices and access to quality-assured and lower-cost HIV treatment and prevention tools to sustain over the long-term, owing to HIV infections averted,” said Hui Yang, Head of Supply Operations at the Global Fund.

The Global Fund and PEPFAR will work closely with CIFF and BMGF to support countries and communities to implement national and sub-national HIV long-acting injectable PrEP programs, alongside WHO, Unitaid, UNAIDS and others.

“Far too many people at high risk of HIV infection lack access to lifesaving treatments,” said Trevor Mundel, President of Global Health at BMGF. “Our mission is to work alongside communities and partners to change that by ensuring access to game-changing products like lenacapavir that can protect individuals from HIV infection and help to end the disease.”

The Global Fund plays a proactive, deliberate, and strategic role in shaping markets to facilitate access to products and improve health outcomes for people living with HIV, TB, and malaria. Through its NextGen Market Shaping approach, the Global Fund is contributing to health outcomes by leveraging its position to facilitate healthier global markets for health products, today and in the future. This vision reiterates the importance of a proactive approach and emphasizes the

linkage between the Global Fund's market-shaping efforts and its focus on health outcomes.

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