

AFRO CAB

Afrocab Treatment Access Partnership

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Afrocab Statement to Daniel O'Day, CEO of Gilead Sciences

One step closer to a game-changer for HIV prevention, but a long road ahead: **We must act now to accelerate equitable access to lenacapavir and avoid the pitfalls and roadblocks experienced with CAB-LA**

Daniel O'Day
Gilead Sciences
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Foster City, CA 94404
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Dear Mr. Daniel O'Day,

Today Gilead [announced groundbreaking results](#) from an interim analysis of its efficacy trial of lenacapavir (LEN) for PrEP, a drug already USFDA approved for treatment. With zero HIV acquisitions and 100% efficacy, LEN has the potential to radically transform HIV prevention and the lives of millions at risk of HIV acquisition. Replacing 365 pills of oral PrEP with just two injections is a life-changing transition and urgently needed option, as millions of our brothers and sisters, friends, and neighbors face challenges of stigma, pill burden, and adherence, leaving them unprotected against HIV acquisition.

Gilead's [PURPOSE 1 trial](#) was designed to investigate the use of LEN among a population facing a disproportionate burden of HIV infections and in urgent need of more acceptable, effective PrEP options. In sub-Saharan Africa, there were over 575 new HIV acquisitions every single day among adolescent girls and young women (AGYW) aged 15-24 years. We congratulate Gilead's paradigm-shifting scientific breakthrough and commend their focus on AGYW in low- and middle-income countries (LMICs).

We also note, with excitement and great interest, Gilead's plans to meet with community partners to discuss an access strategy for LEN. As we have seen in decades of experience with antiretrovirals (ARVs) for HIV treatment and prevention, ensuring access to affordable, generic versions of LEN will be critical for rapidly curbing new infection rates. It has been nearly a year since Afrocab released its [first statement on LEN access](#) following a convening of community advocates in Nairobi, Kenya. As we stated in that letter, we must learn from experience – the delays between study results and LMIC access to CAB-LA remain unacceptable and cannot be repeated.

To forge a new pathway forward for LEN, we call on stakeholders to act now. After thousands of our community members have taken part in clinical trials for LEN and other injectable PrEP products, it is time that pharmaceutical companies, governments, and donors play their part in driving access among the communities that supported the science.

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A Call to Action

We call on stakeholders to initiate the following actions immediately:

> ALL STAKEHOLDERS:

- As progress is made towards the development of this important new tool for prevention, we must not forget about the **role LEN can play in treatment**. As such, there must be a coordinated effort to enable access to long-acting treatments where appropriate AND evolve our strategies to think holistically at how we work together to truly end the epidemic for everyone, everywhere.
- Commit to the inclusion of regional and local stakeholders involved in implementation to have a seat at the table in the development of decisions and action plans that will directly impact them and enable their success.

> Gilead:

- Commit to generic licensing for LEN for PrEP and treatment to ensure affordable access in LMICs.
- Commit to making the innovator product available and accessible for all until generic licensees have the relevant approvals and product available in LMICs.
- Clearly communicate study results as quickly as possible, working in partnership with communities to disseminate data and evidence.
- Commit to broad country marketing registration filings for LEN to facilitate procurement and importation to assure access.

> Donors:

- The Bill and Melinda Gates Foundation, Unitaid, CIFF, the Global Fund, PEPFAR, USAID and other donors must come together to rapidly support and execute the market-shaping and implementation science investments required to bring LEN to market as quickly as possible.

> Governments

- Ensure there is no delay in reviewing LEN marketing registration filings, streamlining processes for maintaining registrations, updating guidelines, and developing introduction plans for wide scale delivery.

> WHO

- Accelerate policy and guidance development processes, ensuring a Guidelines Development Group is formed as quickly as possible.
- Support facilitated registration in-country for LEN after WLA regulatory approval.

Sincerely,



Kenly Sikwese
EXECUTIVE DIRECTOR