August 28, 2025

Dear Community Advocates,

I want to acknowledge receipt of your letter from August 14 and express my gratitude for your advocacy on behalf of communities affected by HIV. I am pleased to respond to the issues you raise and share more information on our commitment to ensuring access.

We share your goal of ensuring that people who may benefit from PrEP have timely, sustainable access to innovative prevention options. As we seek to maximize our global impact, Gilead is making thoughtful decisions informed by evidence and consultation to prioritize the most urgent needs, leverage the biggest opportunities and amplify our impact through partnership and collaboration. We recognize the importance of transparency, and will continue to share updates on our progress through avenues such as our dedicated access page for long-acting PrEP on Gilead.com.

In preparing for the introduction of lenacapavir for PrEP, we were intentional in conducting outreach to more than 100 global health stakeholders –including advocates and organizations that have signed on to your letter – to inform the design of our approach to access. Through these consultations, four essential priorities surfaced:1) deliver lenacapavir for PrEP with **speed**, 2) at sufficient **volume** to meet demand, 3) at prices that enable **widespread availability**, and 4) in coordination with **partners on the ground**. These priorities guide every step of our strategy.

A key pillar in our commitment to access is our voluntary licensing program for lenacapavir. Generic manufacturers will be instrumental to achieving broad, sustainable access in high-incidence, resource-limited countries. Even before the first regulatory filing, Gilead had secured royalty-free agreements with six generic manufacturers to cover 120 high-incidence, resource-limited countries that account for a large share of the global HIV burden. These agreements allow for the generic manufacturers to seek regulatory approvals for lenacapavir for PrEP and provide access in sufficient volumes to meet patient demand and result in generic competition to drive down costs. Gilead is working closely with the licensees to accelerate their readiness and ability to deliver lenacapavir at scale as soon as possible. For example, we have completed technology transfers and are providing assistance with bioequivalence studies and regulatory filings.

Until then, Gilead is committed to supplying lenacapavir at no profit to Gilead in countries covered by the voluntary licenses. Guided by the imperative to deliver sufficient volumes at speed, we are collaborating with global procurement bodies to prioritize regions with the most severe and urgent needs. By the end of 2025, Gilead intends to complete regulatory submissions for lenacapavir for PrEP in 18 countries[1] that represent approximately 70% of the HIV burden in the region covered by the voluntary license.

To help speed regulatory reviews and ensure that Gilead-supplied lenacapavir is available at sufficient volumes when approved, we have also pursued several global regulatory processes and procurement collaborations:

[1] [1] These countries, also listed on our website, are: Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia, Zimbabwe, Philippines, Thailand and Vietnam.

- In July 2025, Gilead finalized an agreement with the Global Fund. Through the agreement, Gilead will supply enough doses of lenacapavir for PrEP to reach up to two million people in primarily low- and lower-middle-income countries (LLMICs) over three years. The agreement plays a central role in enabling timely access to lenacapavir in countries covered by the voluntary license.
- Gilead intentionally selected the EU-Medicines for All (EU-M4all) pathway to streamline national reviews and facilitate global reviews, including WHO Prequalification. Eight LLMICs—Kenya, Nigeria, South Africa, Uganda, Zambia, Zimbabwe, Thailand and Vietnam—participated in the EU-M4all process as scientific experts, helping to facilitate national regulatory evaluations in these countries.
- In August, Gilead submitted lenacapavir for PrEP for WHO Prequalification, immediately following a positive EU-M4all opinion. WHO has announced that it expects to conclude the prequalification process by the end of this year.
- We are also actively pursuing the WHO Stringent Regulatory Authority Collaborative Registration Procedure (WHO SRA CRP), which simplifies the product evaluation and approval processes for other national regulatory authorities, accelerating access to lenacapavir for PrEP.

We are working in collaboration with governments and local stakeholders to determine the most efficient and expedient paths to access. This approach ensures we can appropriately respond to specific country needs while relying on streamlined global regulatory mechanisms to enable access to lenacapavir for PrEP.

In middle-income countries that are not among the 120 covered by the voluntary licenses, we are pursuing tailored regulatory strategies to ensure timely access. In March, we submitted registration application in Brazil under its priority review pathway and, now that lenacapavir for PrEP has received FDA and EU approval, we are preparing submissions in Argentina, Mexico, and Peru. We are also exploring options with partners, including the Pan American Health Organization (PAHO), to support countries outside the voluntary license scope across Latin America.

Meaningful access requires more than the availability of an affordable product. It requires building awareness of and demand for PrEP in country after country, equipping healthcare providers and health systems to deliver PrEP to people who need it, securing funding and political support for HIV prevention at the national and global levels, and so much more. Gilead recognizes the distinctiveness and limits of our role, and the critical importance of advocacy in achieving these outcomes.

To that end, we understand the work that Health GAP and other advocacy organizations play in holding all stakeholders accountable. In the context of long-acting PrEP, advocates will be instrumental in driving demand and enlisting governments, healthcare institutions and funders in a concerted effort to end the transmission of HIV. In the case of lenacapavir, for example, such efforts will be critical to ensure that voluntary licensees have a viable and competitive market that drives broad access.

While we may have differing perspectives on some aspects of approach, we are aligned in our shared goal: to end the HIV epidemic for everyone, everywhere. We remain open to continued dialogue and collaboration as we work toward that goal.

Sincerely,
Janet Dorling
Senior Vice President, Intercontinental Region and Gilead Patient Solutions
Gilead Sciences