LONG-ACTING HIV TECHNOLOGIES NAIROBI COMMUNITY MEETING

STATEMENT TO DANIEL O'DAY CEO OF GILEAD HEALTH SCIENCES

Lenacapavir has the potential to be a game-changer for HIV prevention and treatment, but we cannot follow the same path as CAB-LA – **Gilead must act now to ensure access in low- and middle-income countries.**

Lenacapavir (LEN) has the potential to radically transform HIV prevention and treatment, not only saving lives but drastically improving the lives of those living with HIV and those at risk of HIV acquisition as a more acceptable, tolerable long-acting antiretroviral (ARV). As a six-monthly subcutaneous injection, LEN for pre-exposure prophylaxis (PrEP) holds the opportunity to replace 365 pills of oral PrEP with just two injections. This is an urgently needed option in our communities where stigma, pill burden, and adherence challenges limit the uptake, continuation, and impact of oral PrEP. In sub-Saharan Africa, every week around 4,000 adolescent girls and young women aged 15-24 years acquire HIV – these unacceptably high rates of new infections will continue if we do not have access to discreet, acceptable HIV prevention products that offer protection without the requirement of daily dosing.

While HIV treatment coverage rates are high across many countries, so are drop-out rates. People living with HIV (PLHIV) urgently need more acceptable treatment options that do not require daily dosing, minimizing stigma, frequent clinic visits, and daily dosing as a reminder of HIV status. LEN has already been approved by the US FDA for the treatment of HIV among those with drug resistance – this is a critical milestone in access to long-acting products, but only the beginning. When combined with other long-acting ARVs, LEN could offer a treatment option that does not require daily dosing, changing the lives of PLHIV.

Although LEN holds enormous potential for our communities, **we must learn from experience. The delays between access to long-acting injectable cabotegravir (CAB-LA) in high-income and low- and middle-income countries (LMICs) are unacceptable**. It has been over 18 months since the US FDA approved CAB-LA – since this time there were over 1 million new HIV infections in LMICs, but not a single person has accessed CAB-LA in LMICs outside of the study participants. While ViiV licensed CAB-LA through the Medicines Patent Pool and several organizations formed the Coalition to Accelerate Access to Long-Acting PrEP in July 2022, these steps and partnerships have not translated into any meaningful action. Announcements, partnerships, and consultations are not acceptable substitutes for access to lifesaving drugs in our communities. Over 19 million people are living with HIV accessing DTG-based regimens in LMICs – rapid, impactful product introduction is achievable. While scaling up injectable PrEP as a novel HIV prevention intervention will require innovative strategies and approaches to address unique challenges in the HIV prevention space, Gilead, donors, governments, and other stakeholders must act quickly, learning from

what has worked and moving beyond approaches that have only led to further delays and inaction.

As communities, thousands of us, our sisters, daughters, and neighbours have taken part in numerous clinical trials for injectable PrEP, and yet drug manufacturers, donors, and other organizations continue to turn their backs on the very communities who contributed to their evidence and regulatory approvals.

We are raising our voices to demand immediate action and an end to these unacceptable delays – Gilead must act now to ensure access to LEN in our communities.

A Call to Action – We demand stakeholders initiate the following actions immediately:

> **Gilead:**
  - Commit to an access plan that ensures rapid, affordable access to LEN for PrEP at scale in LMICs – press releases and ineffective partnerships are not acceptable substitutes. This must involve clear timelines, investigation of innovative regulatory pathways, and appropriate transparency on pricing and volumes.
  - Execute voluntary licensing for LEN for PrEP and treatment to ensure affordable access.
  - Accelerate investigation of combination treatment products for LEN (e.g., with CAB)
  - Commit to sharing study data from PURPOSE 1, 2, and other trials as early as possible and ensuring ongoing transparency with communities on critical access planning steps.
  - Initiate evidence generation among populations not currently covered in trials (e.g., adolescents, pregnant and breastfeeding people) to support regulatory approval for a wide indication.

> **Donors:** Execute timely market-shaping investments for LEN to ensure we do not see the same delays experienced with CAB-LA

> **Re-**engage communities and other key members of the long-acting coalition to ensure continued transparency established in the CAB-LA engagement

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