UNAIDS statement at the World Health Assembly on accelerating access to long-acting HIV prevention: The case of lenacapavir

78<sup>th</sup> World Health Assembly, 16 May 2025, Geneva, Switzerland Distinguished Member States and Distinguished Delegates,

Thank you for the opportunity to address this Assembly on behalf of UNAIDS.

Today, we stand at a pivotal moment in the global HIV response. While we have made tremendous strides in treatment and prevention, progress remains uneven, and new infections persist especially among adolescent girls, young women, and key populations.

To truly sustain and accelerate the HIV response, we must innovate—and ensure those innovations are accessible to all.

Lenacapavir, a long-acting injectable antiretroviral, represents a transformative advance in HIV prevention. Administered just twice a year, it offers a discreet, effective, and convenient option for individuals at substantial risk of HIV. Early clinical data show an efficacy of up to 100% in preventing HIV acquisition in trial populations, underscoring its immense potential to change the trajectory of the epidemic.

But scientific breakthroughs only save lives if people can access them.

Today, we face serious access challenges:

- Innovative health products generally hit the market with prohibitively high prices for most low- and middle-income countries.
- Intellectual property protections restrict the opportunities for enhancing market competition by limiting the ability of generic manufacturers to produce affordable versions.
- Submissions of regulatory registration are not occurring at the needed pace in all countries with high HIV incidence, which further impedes timely rollout.

Without urgent, coordinated action, we risk repeating painful lessons of the past—where life-saving tools reached those in need far too late.

UNAIDS calls on all stakeholders—governments, industry, donors, and multilateral agencies—to act decisively:

- Integrate long-acting prevention into national HIV strategies and UHC frameworks, with strong community leadership and demand creation.
- Ensure regulatory alignment and accelerated submission and approval pathways in high-incidence countries.
- Ensure adequate and sustainable financing for the rollout of long-acting injectables by mobilizing domestic resources, donor support, and catalytic financing models.
- Support expansion of the geographic scope of existing voluntary licensing agreements of lenacapavir to allow access in all countries with high HIV incidence and timely, affordable and more geographically diversified generic production.

Prevention is not a luxury—it is a cornerstone of a sustainable HIV response. Long-acting options like lenacapavir are not only scientific milestones; they are opportunities to reach those who have been left behind by existing tools.

Let us not allow innovation to deepen inequality. Let us make this the moment we turn discovery into delivery—for everyone, everywhere.

Thank you

