ITPC EECA
International Treatment Preparedness Coalition
Eastern Europe and Central Asia

itpc-eeca.org
office@itpc-eeca.org
ITPC EECA
itpceeca

## ITPC EECA Statement on Lenacapavir PrEP: Science Only Thrives with Access.

On June 20, 2024, Gilead Sciences published a press release reporting that the company's twice-yearly injectable HIV-1 capsid inhibitor, lenacapavir (LEN), was 100% effective at preventing HIV among cisgender women ages 16-25 in the Phase 3 PURPOSE-1 trial. There were no HIV infections among the 2,134 South African and Ugandan women who received LEN, versus 16 among 1,068 women given tenofovir + emtricitabine (Truvada) and 39 among 2,136 women given tenofovir alafenamide + emtricitabine (Descovy). These interim results led the trial's Independent Data Monitoring Committee to recommend that all participants be switched to LEN.[1]

In recognition of the significance of this information, and welcoming advancements in HIV prevention and treatment science, we:

1. Urge colleagues to await the publication and presentation of the PURPOSE-1 study results in a peer-reviewed scientific journal, as Gilead's press release excluded information on the frequency and severity of LEN side effects, and the number of study participants who discontinued it. While not doubting the efficacy of LEN, we feel it is necessary to remind everyone of the important principle taught to us by the COVID-19 pandemic: "No more science by press release!".

2. Remind colleagues that the value of even the most groundbreaking scientific advances is minimal if they are inaccessible to those who need them most. Gilead has repeatedly deviated from the principles of ensuring equal access to its products, and we have every reason to believe that without proper effort from civil society and other stakeholders, the drug will only be available to high-income countries in the global north and through humanitarian programs, while middle- and upper-middle-income countries, including those with an urgent need for effective HIV prevention, will not get timely access to LEN at a fair price.

3. Call on all stakeholders, upon receiving full scientific information confirming the effectiveness and safety of the drug for HIV prevention, to initiate an inclusive, multilateral process to ensure its global availability, considering lessons learned from both positive and negative experiences with expanding access to other HIV medications, including pricing, patent protection issues, voluntary licensing peculiarities, and more.

4. In the event that individual countries are unable to access this drug at a fair price, we urge governments to use the full range of TRIPS flexibilities to ensure equal access for everyone who needs it in all countries, including issuing compulsory licenses if necessary.

Over the years of HIV activism, we have seen many examples of cutting-edge developments—from the advent of ART to the HPTN 052 study and the Undetectable = Untransmittable strategy. Nonetheless, in 2024, we still live in a world where some people living with HIV lack access to even the simplest life-saving treatments and prevention methods—let alone advanced developments. In the US, where LEN is approved as part of treatment for people with multidrug-resistant HIV, it is priced at $42,250 for the first year, and $39,000 annually for the following years.[2]

Our work will not be finished until people in our region and worldwide are receiving quality HIV prevention, testing, care, and treatment.

«Watch What Matters. Fight for What Is Right. Make Medicines Affordable».

Denis Godlevskiy, Regional coordinator, International Treatment Preparedness Coalition in Eastern Europe and Central Asia

[1] https://www.gilead.com/news-and-press/press-room/press-releases/2024/6/gileads-twiceyearly-lenacapavir-demonstrated-100-efficacy-and-superiority-to-daily-truvada-for-hiv-prevention
[2] https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-approves-gileads-long-acting-hiv-drug-sunlenca-2022-12-22/