



**GTPI denounces that the transnational pharmaceutical company Gilead excludes Brazilians living with HIV from the possibility of accessing the promising drug lenacapavir. Brazil has been excluded, once again, from voluntary license agreements. Gilead presents the voluntary license under the false pretext of expanding access in countries with high HIV incidence and limited resources. In this scenario, Brazil will only be able to buy from Gilead itself at abusive prices. We demand that Brazil exercise its right and duty to issue a compulsory license (patent breaking) to enable local production of lenacapavir and call for widespread social and solidarity mobilization in defense of universal access to health and the SUS!**

Lenacapavir, an innovative drug administered twice a year by subcutaneous injection, has already been approved in the United States and the European Union for the treatment of multi-drug-resistant HIV. However, recent clinical studies (Purpose 1 with women in South Africa and Uganda and Purpose 2 with MSM in Brazil and other countries) demonstrate promising results in its use as pre-exposure prophylaxis (PrEP), with preliminary results showing 100% efficacy against virus transmission.

However, in Brazil, access to this innovation is blocked by three granted patents that prevent the development, production, and commercialization of generic versions of the drug, reinforcing the monopoly and restricting the right to health and limiting treatment and prevention options in the Unified Health System (SUS) until at least 2037. There is no regulatory approval for lenacapavir in Brazil, neither for treatment nor for prevention, despite Brazil's contribution to clinical studies for the drug's development.

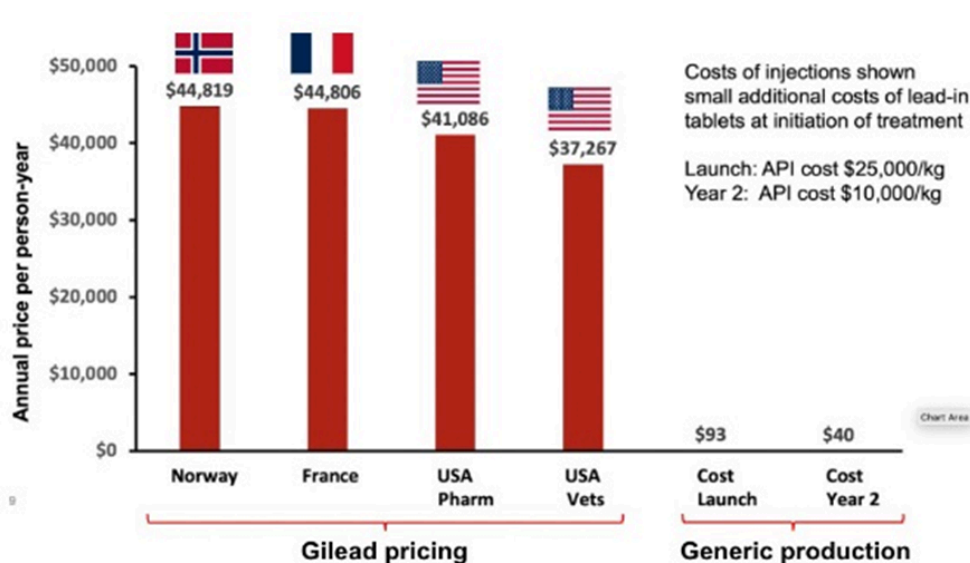
On October 2, Gilead, a U.S.-based company that holds the patent for the drug, announced a voluntary license that allows the manufacturing of generics, but Brazil was once again excluded from the agreement. We were also not considered a priority for the regulatory approval of this medication, according to Gilead's press release.

This exclusion is not surprising, given that international voluntary license agreements consider the World Bank's income classification. Brazil is classified as an “upper-middle-income” country (despite other countries with the same income level being included in this license). This classification ignores the deep socio-economic inequalities, and the exclusion from voluntary licenses like this one disregards the high incidence of HIV, the public health system, and the vulnerabilities of people living with or at risk of HIV infection in Brazil who rely on and need the SUS.

We cannot accept that these arrangements perpetuate the blockage to universal access and comprehensive health care. Lenacapavir has the potential to change the landscape of the AIDS epidemic in Brazil and worldwide, provided it is available at affordable prices for everyone. In the United States and some European countries, the treatment costs over



\$40,000 per person per year! In a recent study, it was estimated that the treatment could be produced on a large scale for approximately \$40 per person per year, considering the inclusion of all low- and middle-income countries, which account for 95% of HIV infections worldwide (Hill et al., 2024). There is still no price estimate for Brazil, but without access to generics, we already know that the price will be an obstacle to its widespread adoption in the country and could jeopardize the sustainability of the universal access program to HIV/AIDS medications.



Source: Hill et al, 2024

Beyond international voluntary licenses, Brazil adopts a model of voluntary licensing often done through secret agreements, such as the Strategic Alliance between Farmanguinhos and GSK/ViiV for the local production of dolutegravir, which lacks transparency and offers medications at prices much higher than the generics available nationally. Brazil has the right and duty to defend public health by issuing compulsory licenses, as provided for in Article 68 of the Industrial Property Law (LPI), to prevent the abuse of the patent system and to favor local production and access to more affordable medicines.

The issuance of a compulsory license for lenacapavir is an urgent measure to ensure the sustainability of SUS and the health of the Brazilian people. We demand that the Brazilian government take a firm stance and issue a compulsory license for lenacapavir, ensuring universal access and strengthening Brazil's response to HIV/AIDS. We call for widespread social and solidarity mobilization in defense of universal access to health and SUS!