PRESS STATEMENT

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Activists at AIDS2024 Demand: Break Gilead's Lenacapavir Monopoly Gilead's Price 10,000% Higher than Target Generic Price for 100% Effective Prevention Shot

(Munich) Today at AIDS 2024, a coalition of activists called for immediate global action to break Gilead's monopoly on lenacapavir, in response to new data showing that generic lenacapavir can be produced at a price one thousand times less than Gilead's price of \$42,250 per year. With mass production, costs for generic lenacapavir are estimated to be initially \$100 per year, with further reductions to \$40 per year as demand increases.

The <u>PURPOSE 1 trial</u> has shown the safety and 100% efficacy of lenacapavir, a twice-yearly injectable for HIV pre-exposure prophylaxis (PrEP), in stopping HIV acquisition among cisgender adult and adolescent women. Worldwide there are 1.3 million infections every year, with one new HIV infection every 24 seconds. Gilead has released no details about their plans for global access—<u>beyond one statement</u>. 25% of all new HIV infections are in Russia, Brazil, Philippines, Ukraine, and Thailand, all countries Gilead routinely excludes from licensing deals.

"100% effectiveness demands 100% access," said Asia Russell of Health GAP, a global HIV advocacy organization. "Lenacapavir for HIV prevention is a potentially pandemic defeating intervention. Gilead has a long track record of undermining global access by excluding middle income countries from voluntary licensing deals and artificially restricting licensees. Therefore, we call on governments to break Gilead's monopoly, by issuing non voluntary licenses, wherever Gilead's patents present a barrier."

"In India, we will fight Gilead's patents on lenacapavir so that we have a supply of generics for all low and middle income countries," said Loon Gangte of the Delhi Network of People Living with HIV (DNP+).

HIV community organizations in India, Argentina, Thailand and Vietnam have filed eight oppositions against Gilead's lenacapavir patent applications—the Thai Network of People living with HIV (TNP+), DNP+, Fundación Grupo Efecto Positivo, and the Vietnam Network of People living with HIV (VNP+).

"In Brazil we are an extremely unequal country with a high HIV incidence. We should not be excluded from access to superior HIV prevention technologies like lenacapavir. Our public health system, which serves 200 million people and 1 million people living with HIV, should not

be forced to pay Gilead's prohibitively high price for this HIV medicine. We have legal mechanisms to guarantee access and safeguard people's lives including compulsory licensing. This should be used to prevent abuse of the patent system and defend people's lives before profit. That's what we call 'putting people first,' " said Susana van der Ploeg, of the Brazilian Interdisciplinary AIDS Association (ABIA).

"To encourage access to lenacapavir, all conditions blocking and delaying R&D, drug registration, and supply of generic lenacapavir should be removed from Gilead's voluntary license, including the control over API supply and high royalty fee," said Chalermsak Kittitrakul of TNP+. "There must be no restrictions preventing generic manufacturers to supply lenacapavir to countries that are excluded from a voluntary license and governments should issue compulsory licenses or make use of other TRIPS flexibilities, if patents are granted."

"Biomedical advances are not going to end HIV unless everyone has access to them," says Solange Baptiste, who heads ITPC Global that leads the Make Medicines Affordable Campaign. "The problem is that pharma has monopoly control over supply and pricing on newer therapeutics. Preventing access to affordable generic medicines in middle income countries shifts the problem—instead of solving it, while governments could use compulsory measures, like refusing any evergreening patent applications to be granted or issuing compulsory license on lenacapavir to ensure full access to it for people in need."

"Reaching the 2030 goal of ending AIDS as a public health threat hinges on Gilead ensuring people have fair access to lenacapavir," said Joyce Ouma, Programmes Officer at Y+ Global, a 27 year old woman living with HIV from Kenya. "They can prevent millions of people acquiring HIV if they fairly and swiftly share Lenacapavir with all low and middle-income countries. Some of these are places where HIV rates are sharply rising, and long-acting medicines would be a crucial tool in reversing this. A twice-yearly injectable would be transformative for young people like me living with or at risk of HIV. It would allow people to live their lives freely without the daily task of taking pills which, for some people often living where HIV isn't fully understood, still carries a sense of stigma that impacts our mental health and wellbeing."

"Lenacapavir could be lifechanging for people at risk of acquiring HIV and could reverse the epidemic if it is made affordable in the countries with the highest rate of new infections," said Dr Helen Bygrave, chronic disease advisor for the MSF Access Campaign. "MSF would be eager to start offering people lenacapavir in our medical programmes, but to do so, we need Gilead to license the drug to other producers through the Medicines Patent Pool in order to allow generic production and supply in all low- and middle-income countries. They also need to urgently publish a price for lenacapavir that is affordable for governments and people everywhere. Research released today shows that one year's supply of lenacapavir could be sold at a profit for under \$100 per person per year, but Gilead currently charges over \$42,000 per year in the US. This kind of pricing undermines the potential of this scientific breakthrough and slows the global effort to turn the tide on HIV and AIDS."