

**GILEAD SIGNS ROYALTY-FREE VOLUNTARY LICENSING AGREEMENTS WITH SIX
GENERIC MANUFACTURERS TO INCREASE ACCESS TO LENACAPAVIR FOR
HIV PREVENTION IN HIGH-INCIDENCE, RESOURCE-LIMITED COUNTRIES**

- License for Companies to Manufacture and Supply High-Quality, Low-Cost Versions of Lenacapavir for 120 Primarily Low- and Lower-Middle Income Countries –*
- Gilead Plans to Price Product at No Profit to the Company and Supply Lenacapavir Until Generic Manufacturers Fully Support Demand –*
- Agreements Also Cover Lenacapavir for HIV Treatment in Heavily Treatment-Experienced Adults with Multi-Drug Resistant HIV –*

Foster City, Calif. – October 2, 2024 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced that it has signed non-exclusive, royalty-free [voluntary licensing agreements](#) with six pharmaceutical manufacturers to make and sell generic lenacapavir, subject to required regulatory approvals, in 120 high-incidence, resource-limited countries, which are primarily low- and lower-middle income countries. The agreements were signed in advance of any global regulatory submissions to enable these countries to quickly introduce generic versions of lenacapavir for HIV prevention, if approved.

The agreements advance Gilead’s strategy to enable broad, sustainable access to lenacapavir for pre-exposure prophylaxis (PrEP) globally if it is approved, and align with Gilead’s vision of ending the HIV epidemic for everyone, everywhere. Gilead will support low-cost access to the drug in high-incidence, resource-limited countries through a two-part strategy: establishing a robust voluntary licensing program, and planning to provide Gilead-supplied product at no profit to Gilead until generic manufacturers are able to fully support demand. Additionally, the agreements cover not only lenacapavir for HIV prevention (pending approval), but also lenacapavir for HIV treatment in heavily treatment-experienced (HTE) adults with multi-drug resistant HIV.

“Given the transformative potential of lenacapavir for prevention, our focus is on making it available as quickly and broadly as possible where the need is greatest,” said Daniel O’Day, Chairman and Chief Executive Officer of Gilead. “Gilead teams have been working with urgency to bring on high-volume generic manufacturers now, so that we can ensure a rapid transition to these voluntary license partners after lenacapavir for PrEP is approved.”

The generic companies that will manufacture and supply lenacapavir to the 120 countries are Dr. Reddy’s Laboratories Limited, Emcure, Eva Pharma, Ferozsons Laboratories Limited, Hetero and Mylan, a subsidiary of Viatriis.

Gilead selected its partners based on rigorous criteria, given the challenges of manufacturing a complex medicine like lenacapavir. All six partners have successfully collaborated with Gilead to produce high-quality generic versions of medicines for HIV or other infectious diseases and are well equipped to produce sterile injectable medicines. In selecting the licensees, Gilead listened to global health advocates and organizations that advised partnering with manufacturers from multiple countries and continents.



Gilead Prioritizing Registration in 18 Countries with High Incidence to Provide Lenacapavir Until Generic Versions are Available

The licensees announced today will build manufacturing capacity for lenacapavir as quickly as possible, but this process will take time. To provide Gilead-supplied lenacapavir until generic versions are available, Gilead is prioritizing registration in 18 countries that represent about 70% of the HIV burden in the countries named in the license. These countries, identified in consultation with external partners, are Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Philippines, Rwanda, South Africa, Tanzania, Thailand, Uganda, Vietnam, Zambia and Zimbabwe.

Gilead to Begin Regulatory Filings for Lenacapavir for PrEP by the End of 2024

Earlier this year, two pivotal Phase 3 trials of lenacapavir for PrEP, [PURPOSE 1](#) and [PURPOSE 2](#), were both unblinded early because they met their key efficacy endpoints of superiority of twice-yearly lenacapavir to once-daily oral Truvada[®] and background HIV incidence. PURPOSE 1 enrolled cisgender women in South Africa and Uganda, and PURPOSE 2 enrolled cisgender men, transgender men, transgender women and non-binary individuals in Argentina, Brazil, Mexico, Peru, South Africa, Thailand and the United States who have sex with partners assigned male at birth. Gilead is committed to ensuring that individuals who participated in the PURPOSE studies have access to lenacapavir for PrEP post-trial.

Based on data from these trials, Gilead will begin a series of global regulatory filings by the end of 2024. For high-incidence, resource-limited countries, Gilead is exploring frameworks such as the European Medicines Agency's EU Medicines for All with the aim of expediting both national regulatory procedures and the attainment of WHO prequalification. Updates on regulatory filings for lenacapavir for PrEP will be shared as discussions with regulatory bodies progress.

Extensive Consultations with HIV Community

Gilead's strategy to enable broad access to lenacapavir for PrEP reflects input from more than 100 global health stakeholders. Through these discussions, four essential priorities have consistently emerged: delivering long-acting PrEP with speed, at sufficient volume to meet demand, at prices that enable widespread availability and in coordination with partners on the ground. These priorities are guiding every step of Gilead's strategy.

The agreements also build upon Gilead's two decades of innovation and leadership in global access to medicines. Gilead's partnerships with generic drug manufacturers have helped enable millions of people to benefit from high-quality, low-cost therapies for HIV, viral hepatitis and COVID-19. More than 30 million treatments for HIV, HBV, HCV and COVID-19 have been made available in low- and middle-income countries as a result of partnerships with generic licensees, governments and NGOs.

The use of lenacapavir for the prevention of HIV is investigational, is not approved anywhere globally, and the safety and efficacy for this use have not been established.

There is currently no cure for HIV or AIDS.

About the PURPOSE Program



Gilead's landmark PURPOSE program is the most comprehensive and diverse HIV prevention trial program ever conducted. The program comprises five HIV prevention trials around the world that are focused on innovation in science, trial design, community engagement and health equity.

The PURPOSE trials are evaluating the safety and efficacy of an investigational, twice-yearly injectable medicine, lenacapavir, to reduce the chance of getting HIV. The Phase 2 and 3 program, consisting of PURPOSE 1-5, is assessing the potential of lenacapavir to help a diverse range of people around the world who could benefit from PrEP.

More information about the PURPOSE program, including individual trial descriptions, populations and locations, can be found at www.purposestudies.com.

About Lenacapavir

Lenacapavir is approved in multiple countries for the treatment of adults with multi-drug resistant HIV in combination with other antiretrovirals. The use of lenacapavir for HIV prevention is investigational and the safety and efficacy of lenacapavir for this use have not been established.

The multi-stage mechanism of action of lenacapavir is distinguishable from other currently approved classes of antiviral agents. While most antivirals act on just one stage of viral replication, lenacapavir is designed to inhibit HIV at multiple stages of its lifecycle and has no known cross resistance exhibited in vitro to other existing drug classes.

Lenacapavir is being evaluated as a long-acting option in multiple ongoing and planned early and late-stage clinical studies in Gilead's HIV prevention and treatment research program. Lenacapavir is being developed as a foundation for potential future HIV therapies with the goal of offering both long-acting oral and injectable options with several dosing frequencies, in combination or as a mono agent, that help address individual needs and preferences of people and communities affected by HIV.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including Gilead's ability to initiate, progress and complete clinical trials in the anticipated timelines or at all, and the possibility of unfavorable results from ongoing and additional clinical trials, including those involving lenacapavir (such as the PURPOSE 1 trials); uncertainties relating to regulatory applications and related filing and approval timelines, including regulatory applications for lenacapavir for PrEP, and the risk that any regulatory approvals, if granted, may be subject to significant limitations on use or subject to withdrawal or other adverse actions by the applicable regulatory authority; the possibility that Gilead may make a strategic decision to discontinue development of lenacapavir for indications currently under evaluation and, as a result, lenacapavir may never be successfully commercialized for such indications; Gilead's ability to effectively manage the supply and distribution of lenacapavir, including through direct supply as well as indirect supply through the voluntary licensing agreements, and the ability of the parties to meet potential demand for lenacapavir, in each case, subject to necessary regulatory approvals; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and factors are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and is cautioned not to place undue reliance on these forward-looking



statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation and disclaims any intent to update any such forward-looking statements.

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U.S. full Prescribing Information for Truvada, including Boxed Warning, and lenacapavir are available at www.gilead.com.

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