Communiqué de presse

EUROPEAN COMMISSION AUTHORIZES TWICE-YEARLY YEYTUO® (LENACAPAVIR) FOR HIV PREVENTION

– Yeytuo® is the First and Only European Commission (EC)-Authorized HIV PrEP Option Offering 6 Months of Protection –

– Accelerated EC Decision Comes After U.S. FDA Approval in June –

Foster City, Calif., August 26, 2025 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Commission (EC) has granted marketing authorization for Yeytuo® (lenacapavir)—the company's twice-yearly injectable HIV-1 capsid inhibitor—for use as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents with increased HIV-1 acquisition risk who weigh at least 35kg. Yeytuo is the first and only twice-yearly PrEP option to be approved for use in the European Union's 27 member states, as well as Norway, Iceland and Liechtenstein.

The marketing authorization application (MAA) was reviewed under an accelerated timeline based on the assessment by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) that twice-yearly Yeytuo is a product of major interest for public health. In July, the CHMP adopted a positive opinion recommending Yeytuo for EC authorization. Additionally, lenacapavir will be granted one additional year of market protection in the EU as a result of the new indication, following a scientific evaluation prior to authorization that it brought significant clinical benefit in comparison to existing therapies.

"Yeytuo's rapid authorization by the European Commission underscores the rigor of our clinical data and the transformative potential of Yeytuo to help address the urgent unmet need in HIV prevention across Europe," said Dietmar Berger, MD, PhD, Chief Medical Officer at Gilead Sciences. "This milestone is a testament to the 17 years of Gilead research that delivered this breakthrough PrEP medication, underpinned by decades of leadership in HIV innovation."

The EC authorization follows approval by the U.S. Food and Drug Administration (FDA) in June, as well as the issuance of guidelines by the World Health Organization (WHO) in July that recommended twice-yearly lenacapavir as an additional PrEP option for HIV prevention.

"With around 25,000 new HIV diagnoses in the EU and European Economic Area every year, it's clear that current prevention options are not working for everyone who needs or wants them, especially among vulnerable populations," said Jean-Michel Molina, MD, Université Paris Cité, Professor of Infectious Diseases and Head of the Infectious Diseases Department at the Saint-Louis and Lariboisière Hospitals. "Yeytuo's novel twice-yearly dosing schedule and high efficacy could be the transformative HIV prevention option in Europe we've been waiting for to help us reduce new infections and make real progress toward ending the HIV epidemic."

EC authorization of Yeytuo is supported by efficacy and safety data from two Phase 3 trials

The EC authorization of Yeytuo was supported by data from the Phase 3 PURPOSE 1 and PURPOSE 2 trials conducted by Gilead. In the PURPOSE 1 trial (NCT04994509), data at the primary analysis showed

that administration of twice-yearly subcutaneous lenacapavir led to zero HIV infections among 2,134 participants, 100% reduction in HIV infections and superiority of prevention of HIV infections when compared with once-daily oral Truvada® (emtricitabine 200mg and tenofovir disoproxil fumarate 300mg; F/TDF) in cisgender women in sub-Saharan Africa. In the PURPOSE 2 trial (NCT04925752), at the primary analysis there were two HIV infections among 2,179 participants in the twice-yearly subcutaneous lenacapavir group, demonstrating 99.9% of participants did not acquire HIV infection and superiority of prevention of HIV infections when compared with once-daily oral Truvada among a broad and geographically diverse range of cisgender men and gender-diverse people. In both trials, lenacapavir demonstrated superiority of prevention of HIV infections when compared with background HIV incidence (bHIV) and was generally well-tolerated, with no significant or new safety concerns identified. Data from both trials were published in *The New England Journal of Medicine* and based in part on the trial results, in December 2024 the journal *Science* named lenacapavir its 2024 "Breakthrough of the Year."

Continued global regulatory filings and milestone partnerships for lenacapavir for PrEP

Gilead is executing a global access strategy informed by health advocates and organizations that prioritizes speed and enables the most efficient paths for regulatory review, approval of and access to twice-yearly lenacapavir for PrEP. Beyond approvals in the U.S. and EU, Gilead has also filed for regulatory review of twice-yearly lenacapavir for PrEP with authorities in Australia, Brazil, Canada, South Africa and Switzerland. Additionally, now that lenacapavir for PrEP has received approvals in the U.S. and the EU, Gilead is preparing filings in Argentina, Mexico and Peru.

Following the recent EU-Medicines for all (EU-M4all) positive opinion for lenacapavir for PrEP, Gilead intends to pursue submissions to national regulatory authorities in low- and middle-income (LMIC) countries utilizing the opinion to facilitate accelerated review timelines. This includes priority registrations covering 18 countries that represent 70% of the HIV burden of the 120 countries named in Gilead's previously announced voluntary licensing agreements. The EU-M4all procedure also enables a streamlined assessment for World Health Organization (WHO) prequalification. Additionally, in July, Gilead announced a strategic partnership agreement with The Global Fund to Fight AIDS, Tuberculosis and Malaria to supply lenacapavir for PrEP for up to two million people in primarily low- and lower-middle-income countries, if approved.

For more information about Gilead's access strategy for LMICs, see Gilead's LMIC access page.

Lenacapavir for PrEP is not approved by any regulatory authority outside of the U.S. and the EU.

There is currently no cure for HIV or AIDS.

About Lenacapavir

Lenacapavir is approved in multiple countries as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV in adults and adolescents who are at risk of HIV acquisition. Lenacapavir is also approved in multiple countries for the treatment of multi-drug-resistant HIV in adults, in combination with other antiretrovirals.

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. The journal *Science* named lenacapavir its 2024 "Breakthrough of the Year."

EU Indication for Yeytuo®

Yeytuo® injection is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents with increased HIV-1 acquisition risk weighing at least 35kg.

U.S. Indication for Yeztugo®

Yeztugo® (lenacapavir) injection, 463.5 mg/1.5 mL, is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents (≥35kg) who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating Yeztugo.

About Gilead HIV

For more than 35 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention and cure research. Gilead researchers have developed 13 HIV medications, including the first single-tablet regimen to treat HIV, the first antiretroviral for pre-exposure prophylaxis (PrEP) to help reduce new HIV infections, and the first long-acting injectable HIV treatment medication administered twice-yearly. Our advances in medical research have helped to transform HIV into a treatable, preventable, chronic condition for millions of people.

Gilead is committed to continued scientific innovation to provide solutions for the evolving needs of people affected by HIV around the world. Through partnerships, collaborations and charitable giving, the company also aims to improve education, expand access and address barriers to care, with the goal of ending the HIV epidemic for everyone, everywhere. Gilead was recognized as one of the leading philanthropic funders of HIV-related programs in a report released by Funders Concerned About AIDS.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, COVID-19, cancer and inflammation. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

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 PURPOSE 1 and PURPOSE 2); 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; the risk that physicians may not see the benefits of prescribing Yeztugo/Yeytuo for PrEP; Gilead's ability to effectively manage the access strategy relating to lenacapavir, 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, 2025, 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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Ce communiqué de presse est la version originale du communiqué de presse diffusé par Gilead.

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