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Gilead's Twice-Yearly Lenacapavir for HIV Prevention Reduced HIV Infections by 96% and Demonstrated Superiority to Daily Truvada® in Second Pivotal Phase 3 Trial

– 99.9% of Participants Did Not Acquire HIV Infection in the Lenacapavir Group, with 2 Incident Cases Among 2,180 Participants –

– PURPOSE 2 Trial Results for Cisgender Men and Gender-Diverse People Add to the Body of Evidence for the Investigational Use of Lenacapavir for HIV Prevention –

– Gilead Stopped the Blinded Phase of the Trial at Interim Analysis and Will Offer Open-Label Lenacapavir to All Participants –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced the results of an interim analysis from a second pivotal Phase 3 clinical trial investigating the use of the company's twice-yearly injectable HIV-1 capsid inhibitor, lenacapavir. Lenacapavir reduced HIV infections by 96% compared to background HIV incidence (bHIV). There were 2 incident cases among 2,180 participants, corresponding to 99.9% of participants not acquiring HIV infection in the lenacapavir group. Twice-yearly lenacapavir also demonstrated superiority to once-daily Truvada ® (emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg; F/TDF).

The trial, PURPOSE 2 (NCT04925752), includes cisgender men, transgender men, transgender women, and gender non-binary individuals in Argentina, Brazil, Mexico, Peru, South Africa, Thailand and the United States who have sex with partners assigned male at birth. At interim analysis, the independent Data Monitoring Committee (DMC) confirmed that the PURPOSE 2 trial met its key efficacy endpoints of superiority of twice-yearly lenacapavir to both bHIV (primary endpoint) and once-daily oral Truvada (secondary endpoint) for pre-exposure prophylaxis (PrEP). Therefore, the DMC recommended that Gilead stop the blinded phase of the trial and offer open-label lenacapavir to all participants.

"With such remarkable outcomes across two Phase 3 studies, lenacapavir has demonstrated the potential to transform the prevention of HIV and help to end the epidemic," said Daniel O'Day, Chairman and Chief Executive Officer of Gilead. "Now that we have a comprehensive dataset across multiple study populations, Gilead will

work urgently with regulatory, government, public health and community partners to ensure that, if approved, we can deliver twice-yearly lenacapavir for PrEP worldwide, for all those who want or need PrEP."

This is the second pivotal Phase 3 trial to demonstrate superior efficacy for twice-yearly lenacapavir for the investigational use of HIV prevention as PrEP. In June 2024, the PURPOSE 1 trial, studying lenacapavir for PrEP among cisgender women in sub-Saharan Africa, was also unblinded early because it met its key efficacy endpoints.

The data from the PURPOSE 1 and PURPOSE 2 trials will support upcoming regulatory filings so that twice-yearly lenacapavir for PrEP, if approved, can be made available to multiple populations and communities around the world who are most in need of additional HIV prevention choices. Updates on regulatory filings for lenacapavir for PrEP will be shared as discussions with regulatory bodies progress. Gilead will begin a series of global regulatory filings by the end of 2024. This could support the initial launch of the first and only twice-yearly HIV prevention choice in 2025.

Gilead is executing an access strategy that prioritizes speed and enables the most efficient paths for the regulatory review and approval of lenacapavir for PrEP in regions around the world. This strategy will prioritize high-incidence, low-resource countries, which are primarily low- and lower-middle income countries. Gilead is committed to making lenacapavir available in the countries where the need is greatest, including expediting voluntary licensing partners to supply high-quality, low-cost versions of lenacapavir. Gilead is actively working to finalize these contracts.

Topline PURPOSE 2 Data

PURPOSE 2, a phase 3, double-blind, multicenter, randomized study, is evaluating the safety and efficacy of twice-yearly subcutaneous lenacapavir for PrEP versus once-daily oral Truvada and background HIV incidence (bHIV) in more than 3,200 cisgender men, transgender men, transgender women and gender non-binary individuals aged 16 years or older who have sex with partners assigned male at birth. There were 88 trial sites in Argentina, Brazil, Mexico, Peru, South Africa, Thailand and the United States.

Study participants were randomized in a 2:1 ratio to lenacapavir and Truvada, respectively. Because effective PrEP options already exist, there is broad consensus in the PrEP field that a placebo group would be unethical; thus, the trial used bHIV as the primary comparator and Truvada as a secondary comparator.

There were 2 incident cases among 2,180 participants in the lenacapavir group (incidence 0.10 per 100 person-years); 99.9% of participants did not acquire HIV in the

lenacapavir group. The results demonstrated superiority of twice-yearly lenacapavir over bHIV (incidence 2.37 per 100 person-years), with 96% relative risk reduction (incidence rate ratio 0.04, p<0.0001). There were 9 incident cases among 1,087 individuals in the Truvada group (incidence 0.93 per 100 person-years). Twice-yearly lenacapavir was 89% more effective than once-daily Truvada (incidence rate ratio 0.11, p=0.00245). In the trial, lenacapavir and Truvada were generally well-tolerated and no significant or new safety concerns were identified.

More detailed data from PURPOSE 2 will be presented at a future conference.

“The difficulty some people can experience with taking an oral pill every day, including challenges with adherence and stigma, have hindered uptake and persistence of the standard of care for too long, thus blunting PrEP’s impact on HIV prevention,” said PURPOSE 2 Principal Investigator Onyema Ogbuagu, MBBCh, FACP, FIDSA, Associate Professor of Medicine and Pharmacology at Yale School of Medicine and Director of the Yale Antivirals and Vaccines Research Program. “The incredible efficacy demonstrated in the PURPOSE 2 trial, the potential benefits of a twice-yearly injection, and the diversity of trial sites and participants show the impact that lenacapavir for PrEP could have for people around the world who need new choices to reduce their chances of acquiring HIV. This breakthrough adds significantly to our arsenal of tools to move us closer to achieving an AIDS-free generation.”

“In the United States, the stubbornly high rate of HIV diagnoses—especially in the U.S. South, and particularly among gay and bisexual men of color and transgender people—demands novel approaches to help people prevent HIV acquisition,” said Colleen Kelley, MD, MPH, Professor of Medicine at Emory University and a PURPOSE 2 Principal Investigator. “Because adherence to oral products can be challenging for some people, twice-yearly injectable lenacapavir for PrEP has the potential to be one of the most impactful interventions we could have to drive down new infections and bring us closer to ending the HIV epidemic in the United States.”

The use of lenacapavir for the prevention of HIV is investigational and has not been determined to be safe or efficacious and is not approved anywhere globally.

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.

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 12 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.

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 Truvada and 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; 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.

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

For more information about Gilead, please visit the company's website at www.gilead.com , follow Gilead on X/Twitter (@Gilead Sciences) and LinkedIn (@Gilead-Sciences).