Updated Statement on Access Planning in High-Incidence, Resource-Limited Countries for Lenacapavir for HIV Prevention

Foster City, Calif., September 12, 2024 – Today, Gilead announced that the company's twice-yearly injectable HIV-1 capsid inhibitor, lenacapavir, demonstrated superiority to background HIV incidence (bHIV) and once-daily oral Truvada® for the investigational use of HIV prevention at an interim analysis of a second pivotal Phase 3 clinical trial.

The trial, PURPOSE 2, 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.

This is the second pivotal Phase 3 trial to demonstrate superior efficacy for twice-yearly lenacapavir for the investigational use of HIV prevention as pre-exposure prophylaxis (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.

As part of the company's ongoing commitment to communities affected by HIV, we are pursuing a strategy to enable broad, sustainable access to lenacapavir for PrEP globally if approved. A key component of this strategy is to deliver lenacapavir swiftly, sustainably and in sufficient volumes, if approved, to high-incidence, resource-limited countries, which are primarily low- and lower-middle-income countries. We are in active discussions with the HIV community and are providing details about our plans as soon as we can.

Getting lenacapavir to high-incidence, resource-limited countries

Although lenacapavir for PrEP is not currently approved anywhere in the world, Gilead continues to move with urgency to develop a robust direct voluntary licensing program to expedite access to lenacapavir for PrEP once approved in high-incidence, resource-limited countries. We are actively working to finalize contracts and are pleased to share that they will cover not only lenacapavir for PrEP, but also lenacapavir for the treatment of HIV-1 infection in heavily treatment-experienced (HTE) adults with multi-drug resistant HIV-1 infection.

Gilead is committed to making lenacapavir available in the countries where the need is greatest until voluntary licensing partners are able to supply high-quality, low-cost versions of lenacapavir.

Regulatory status of lenacapavir for HIV prevention and next steps

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 authorized for multiple populations and communities around the world who are most in need of additional HIV prevention choices. Gilead is executing an access strategy that prioritizes speed and enables the most efficient paths for the regulatory approval of lenacapavir for PrEP in regions around the world, including prioritizing high-incidence, low-resource countries. Gilead will begin a series of global regulatory filings by the end of 2024.

We are exploring frameworks intended to facilitate faster access in target populations and countries such as the European Medicines Agency's EU Medicines for All, and the World Health Organization's collaborative review and prequalification procedures. EU Medicines for All provides opinion on medicines intended for use outside of the EU and can run in parallel with an EU centralized filing. We believe these frameworks could enable Gilead to secure approvals in key high-incidence, resource-limited countries as quickly as possible in relation to an EU approval.

Updates on regulatory filings for lenacapavir for PrEP will be shared as discussions with regulatory bodies progress.

Pricing yet to be determined for lenacapavir for HIV prevention

Lenacapavir for PrEP remains an investigational drug until approved by regulatory authorities. While Gilead awaits the regulatory filing of lenacapavir for PrEP, it is too early to state the price.

Gilead is committed to access pricing for high-incidence, resource-limited countries. The current price for the approved indication in the heavily treatment-experienced HIV population will not be our reference.

Extensive consultations with HIV community

Our access strategy for high-incidence, resource-limited countries reflects extensive consultations with HIV-affected communities worldwide as well as governments, advocates, multilateral organizations, individuals who need or want PrEP, and community partners. 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 our strategy planning. We are also applying learnings from our two decades of innovation and leadership in global access to medicines. In 2023 alone, more than 20 million HIV and hepatitis B treatments based on Gilead therapeutics were made available to people living in low- and lower-middle-income countries. In that same year, more than 11 million units of Gilead-branded medicines were delivered to nearly 250,000 individuals in these countries.

We thank the people and organizations who have provided counsel and guidance on our lenacapavir for PrEP access strategy. We look forward to sharing further updates as milestones are reached.

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

About Gilead HIV

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, and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

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 funder of HIV-related programs in a report released by Funders Concerned About AIDS.

Forward-Looking Statements

This statement 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.

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).

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