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For Immediate Release

**GILEAD'S INVESTIGATIONAL SINGLE-TABLET REGIMEN OF BICTEGRAVIR AND
LENACAPAVIR FOR HIV-1 TREATMENT MEETS PRIMARY ENDPOINT IN PHASE 3
ARTISTRY-1 TRIAL**

*– The Novel HIV Therapy has the Potential to Expand Options for Virologically Suppressed Adults
Treated with Complex ART Regimens –*

– Phase 3 Results from ARTISTRY-1 and 2 Trials will Form the Basis of Regulatory Submissions –

Foster City, Calif., November 13, 2025 – Gilead Sciences, Inc. (NASDAQ: GILD) today announced positive topline results from the Phase 3 ARTISTRY-1 trial. The open-label trial evaluated the treatment responses of adults with HIV who are virologically suppressed switching from a multi-tablet regimen to an investigational single-tablet regimen of bictegavir 75 mg/lenacapavir 50 mg (BIC/LEN). BIC/LEN efficacy was found to be statistically non-inferior to multi-tablet regimens. Gilead plans to file the Phase 3 data from the ARTISTRY trials with regulatory authorities and submit the detailed findings for presentation at a future scientific congress.

In ARTISTRY-1, the once-daily single-tablet regimen of BIC/LEN met the primary success criterion for non-inferiority to baseline multi-tablet antiretroviral therapy regimens. The primary efficacy endpoint was the percentage of participants with HIV-1 RNA levels ≥ 50 copies/mL at Week 48, defined by the FDA snapshot algorithm. In the trial, BIC/LEN was generally well tolerated, with no significant or new safety concerns identified.

People living with HIV-1 on complex regimens are unable to benefit from guideline-recommended STRs due to reasons of pre-existing resistance, tolerability and drug-drug interactions, and therefore may face challenges such as high pill burden, complicated adherence, and reduced quality of life. A single-tablet regimen combining bictegavir and lenacapavir could offer a new medication option with convenient dosing for people living with HIV treated with complex regimens. At baseline, participants enrolled in ARTISTRY-1 were taking between 2 and 11 pills per day for their HIV treatment, with ~40% taking their antiretrovirals more than once a day.

“Developing new effective, convenient regimens for those left behind by advances in medical research is necessary to close the unmet HIV treatment gap,” said Chloe Orkin, MBE, Clinical Professor of Infection and Inequities at Queen Mary University of London. “These ARTISTRY-1 trial results demonstrate that a combination regimen of bictegavir and lenacapavir maintains viral suppression in people living with HIV who would otherwise have to take a complex multi-tablet regimen. The findings are significant for those people, many of whom have lived with HIV for decades, and who have medical comorbidities of aging and thus take many other medications as well.”

ARTISTRY-1 ([NCT05502341](#)) is a multicenter Phase 2/3 clinical trial comparing the investigational once-daily combination of bicitegravir, a global guidelines-recommended integrase strand transfer inhibitor, and lenacapavir, a first-in-class capsid inhibitor, versus current therapy in people with HIV who are virologically suppressed on complex regimens. In Phase 3, participants were randomized 2:1 to receive a fixed-dose combination of bicitegravir 75 mg/lenacapavir 50 mg or continue their stable baseline complex regimen. The primary endpoint was the proportion of patients with HIV-1 RNA ≥ 50 copies/mL at Week 48 as determined by the US FDA-defined snapshot algorithm. Key secondary endpoints at week 48 included the proportion of participants with virologic suppression (HIV viral load < 50 copies/mL per US FDA Snapshot), change in baseline in CD4 cell count and the proportion of participants with treatment-emergent adverse events (TEAEs).

“People living with HIV who are on complex antiretroviral treatment regimens may experience pill burden, adherence challenges and difficulties with the long-term management of HIV,” said Jared Baeten, MD, PhD, Senior Vice President, Clinical Development, Virology Therapeutic Area Head, Gilead Sciences. “Gilead developed the first single-tablet complete regimen for the treatment of HIV in 2006. Today, innovative single-tablet regimens are still needed to help suit people’s needs, modernizing treatment while helping to sustain viral suppression. By reducing the multi-tablet burden, we hope to improve health outcomes while expanding options.”

Further evaluation of this investigational combination includes the double-blind, Phase 3 ARTISTRY-2 ([NCT06333808](#)) trial which is evaluating the safety and efficacy of switching from BIKTARVY[®] (bicitegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, B/F/TAF) to a fixed-dose combination of bicitegravir 75mg/lenacapavir 50mg in virologically suppressed people with HIV-1. A topline data readout for the primary endpoint is anticipated before the end of the year.

Bicitegravir and lenacapavir in combination are investigational and not approved anywhere globally. Their safety and efficacy have not been established in combination.

There is currently no cure for HIV or AIDS.

About Bicitegravir

Bicitegravir is a global guideline-recommended integrase strand transfer inhibitor (INSTI) with a high barrier to resistance. INSTIs are a class of antiviral agents that target the viral integrase. Bicitegravir is used only in combination with other antiretroviral agents in the treatment of HIV.

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. Lenacapavir was chosen as one of TIME's Best Inventions, recognized on Fortune's Change the World list, named the 2024 Breakthrough of the Year by the journal *Science*, and selected as the 2025 Prix Galien USA Award for Best Pharmaceutical Product.

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 worldwide. Gilead has been repeatedly [recognized](#) as one of the top two leading philanthropic funders of HIV-related programs in a report released by Funders Concerned About AIDS.

Discover more about Gilead's [unique collaborations worldwide](#) and the work to help end the HIV epidemic.

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. In 2025, Gilead announced a planned \$32 billion investment to further strengthen its U.S. footprint to power the next era of discovery, job creation and public health preparedness – while continuing to invest globally to ensure patients everywhere benefit from its scientific innovation. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, Calif.

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 or complete clinical trials or studies within currently anticipated timelines or at all, and the possibility of unfavorable results from ongoing and additional clinical trials or studies, including those involving bicitgravir and lenacapavir (such as ARTISTRY-1 and ARTISTRY-2); uncertainties relating to regulatory applications and related filing and approval timelines, including potential applications for programs and/or indications currently under evaluation, such as the combination of bicitgravir and lenacapavir for HIV-1 infection, 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 these programs and, as a result, these programs may never be successfully commercialized for the indications currently under evaluation; 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 September 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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