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For Immediate Release

GILEAD PRESENTS NEW HIV TREATMENT AND CURE RESEARCH DATA AT CROI 2025, INCLUDING AN INVESTIGATIONAL LONG-ACTING, TWICE-YEARLY THERAPY OPTION

– ***Long-Term Outcomes Reinforce the High Efficacy of Biktarvy® in People with HIV and HBV Coinfection*** –

– ***Investigational Long-Acting, Twice-Yearly Treatment Regimen of Lenacapavir and Broadly Neutralizing Antibodies (bNAbs) Meets Primary Endpoint in Phase 2 Study and Gains Breakthrough Therapy Designation*** –

– ***Late-Breaker Oral Presentation of Phase 2 Results from the First HIV Cure Clinical Trial Conducted in South Africa*** –

Foster City, Calif., March 12, 2025 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced the presentation of late-breaking data and multiple oral presentations from its innovative HIV treatment portfolio and pipeline at the Conference on Retroviruses and Opportunistic Infections (CROI 2025). The new findings reflect a transformative portfolio and a rapidly advancing forward-looking pipeline focused on expanding choices and enhancing outcomes for those with HIV, while continuing to reach towards a cure.

"Gilead is fueling the next wave of innovation in HIV to help end the epidemic globally," said Jared Baeten, MD, PhD, Senior Vice President, Virology Therapeutic Area Head. "Our contributions to CROI spotlight our dedication to scientific discovery, reflect our commitment to addressing the diverse treatment needs and preferences of communities affected by HIV and underscore the vital importance of catalyzing research reaching towards a cure."

Biktarvy Demonstrates High Rates of Viral Suppression in People with HIV/HBV Coinfection

ALLIANCE (NCT03547908) is an ongoing Phase 3 study evaluating Biktarvy versus dolutegravir 50 mg (DTG) + emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg, F/TDF, DTG+F/TDF, in adults with HIV-1/HBV co-infection initiating treatment. The ALLIANCE trial is the first randomized clinical trial of TAF- vs TDF-based regimens in treatment naïve adults with HIV/HBV coinfection. Its goal is to evaluate treatment regimens that may effectively suppress both HIV and HBV. Previously reported results demonstrated the efficacy of both antiretroviral regimens. New outcomes were presented at CROI.

Week 48 outcomes from the open-label extension phase following the 96-week randomized phase reported on the longer-term efficacy and safety of the investigational use of Biktarvy in adults with HIV/HBV coinfection initiating treatment. The newly presented data shows that Biktarvy maintained high rates of HIV-1 (95.4%) and HBV (86.6%) virologic suppression, defined as HIV RNA <50 copies/ mL and HBV

DNA <29 IU/ mL, respectively, in participants (n=89) following a switch to Biktarvy after 96 weeks of treatment with DTG+ F/TDF.

Study drug-related treatment-emergent adverse events (TEAEs) were reported in 19% of participants and most were mild to moderate, with zero discontinuations due to TEAEs. The most commonly reported study drug–related TEAEs were weight gain (9%) and low-density lipoprotein (LDL) cholesterol increased (3%).

These data demonstrate the high rates of viral suppression by Biktarvy in adults with both HIV-1 and HBV switching their treatment to Biktarvy.

The use of Biktarvy in individuals with HIV/HBV co-infection is investigational and the safety and efficacy of this use have not been established.

Breakthrough Therapy Designation Awarded to Long-Acting, Twice-Yearly Investigational Treatment Combination Regimen of Lenacapavir and Broadly Neutralizing Antibodies (bNAbs)

In January 2025, the FDA granted lenacapavir (LEN) with bNAbs (teropavimab [GS-5423, TAB] and zinlirvimab [GS-2872, ZAB]) Breakthrough Therapy Designation, which is intended to expedite the development of new drugs that may demonstrate substantial improvement over available therapy. LEN+TAB+ZAB (LTZ) harbors the potential to be the first long-acting combination treatment regimen with twice-yearly dosing. At CROI 2025, the primary results of a Phase 2 study evaluating the investigational combination of LTZ were presented during an oral session and featured in the press program; those data announced at CROI confirm previously presented Phase 1b results.

The Phase 2 (NCT05729568) open-label study from Gilead's long-acting treatment pipeline evaluated the treatment response of participants receiving the investigational combination of LTZ. Efficacy and safety results were evaluated when virologically suppressed adults switched to LTZ every 6 months versus staying on stable baseline oral antiretroviral regimen. The study met its primary endpoint, which is the proportion of participants with HIV-1 RNA ≥ 50 copies/mL at Week 26 as determined by the US FDA-defined snapshot algorithm.

The Week 26 data demonstrated the high efficacy of the LTZ regimen, with 96% (n=51 of 53) of participants who received LTZ and 96% (n=26 of 27) who received SBR remained virologically suppressed. CD4 cell counts also increased from baseline to week 26 in both groups, with a mean change of +23/µL (n=143) with LTZ and +69/µL (n=203) with SBR. The most common AEs with LTZ were injection site reactions related to subcutaneous LEN administration. There were no serious adverse events (AEs) related to LTZ; there were no infusion reactions related to TAB or ZAB. One participant in the SBR arm discontinued the study due to a serious treatment-related AE.

Teropavimab and zinlirvimab are investigational compounds. The use of these compounds in combination with lenacapavir are investigational. They are not approved by the U.S. Food and Drug Administration or any other regulatory authority for any use, alone or in combination with lenacapavir. Their safety and efficacy are unknown. The use of lenacapavir in virologically suppressed people with HIV is investigational and the safety and efficacy of this use have not been established.

Landmark HIV Cure Clinical Trial Conducted in South Africa

Results from the first HIV cure trial to be conducted in South Africa, sponsored by Gilead, demonstrated that complex cure studies can be successfully conducted, alongside community, in resource-limited settings where great unmet need exists.

As part of Gilead's efforts to find a cure for HIV, the Phase 2a GS-US-382-5445 trial (NCT05281510) enrolled 20 South African cisgender women from the FRESH (Females Rising through Education, Support, and Health) cohort who had received antiretroviral therapy (ART) soon after acquiring HIV and were virologically suppressed for at least 12 months.

Participants received up to 10 oral doses of Gilead's investigational TLR7 agonist, vesatolimod, every 2 weeks starting on day 0, plus IV infusions of broadly neutralizing antibodies (bNAbs) VRC07-523LS and CAP256V2LS, provided by the National Institutes of Health (NIH), on day 7. Participants began an analytical treatment interruption (ATI) on Day 35 and remained off ART until Week 48, or until they met restart criteria. Participants who reached week 48 without meeting ART restart criteria had the option of remaining off ART through the end of study follow-up at Week 60.

Results presented at CROI showed the treatment combination was generally well-tolerated with no treatment-related serious adverse events (TEAEs) reported. The most common study TEAEs were infusion-related reactions (n = 18; 16 grade 1, 2 grade 2). Seventy percent of participants (n=14) met ART restart criteria. Thirty percent (n=6) remained off ART through Week 48, of which 4 remained off ART through Week 60. While the data suggest that the trial regimen alone is not sufficient as an HIV cure regimen, the mechanistic learnings will inform the development of future cure approaches.

There is currently no cure for HIV or AIDS.

Vesatolimod, VRC07-523LS and CAP256V2LS are investigational compounds. They are not approved by the U.S. Food and Drug Administration or any other regulatory authority for any use, alone or in combination. Their safety and efficacy are unknown.

Please see below for U.S. Indications and Important Safety Information, including **Boxed Warning**, for Biktarvy.

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. Science Magazine named lenacapavir its 2024 "Breakthrough of the Year."

About Biktarvy

Biktarvy is a complete HIV treatment that combines three powerful medicines to form the smallest 3-drug, integrase strand transfer inhibitor (INSTI)-based single-tablet regimen (STR) available, offering simple

once-daily dosing with or without food, with a limited drug interaction potential and a high barrier to resistance. Biktarvy combines the novel, unboosted INSTI bictegravir with the F/TAF backbone. Biktarvy is a complete STR and should not be taken with other HIV medicines.

U.S. Indication for Biktarvy

Biktarvy (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg) is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg who have no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically-suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.

U.S. Important Safety Information for Biktarvy

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF) and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.

Contraindications

- **Coadministration** : Do not use BIKTARVY with dofetilide or rifampin.

Warnings and precautions

- **Drug interactions**: See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.
- **Immune reconstitution syndrome**, including the occurrence of autoimmune disorders with variable time to onset, has been reported.
- **New onset or worsening renal impairment**: Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)–containing products. Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min except in virologically suppressed adults <15 mL/min who are receiving chronic hemodialysis. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. *Renal monitoring:* Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus.
- **Lactic acidosis and severe hepatomegaly with steatosis**: Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse reactions

- **Most common adverse reactions** (incidence ≥5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

Drug interactions

- **Prescribing information**: Consult the full prescribing information for BIKTARVY for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.
- **Enzymes/transporters**: Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.
- **Drugs affecting renal function**: Coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

Dosage and administration

- **Dosage**: Adult and pediatric patients weighing ≥25 kg: 1 tablet containing 50 mg bictegravir (BIC), 200 mg emtricitabine (FTC), and 25 mg tenofovir alafenamide (TAF) taken once daily with or without food. Pediatric patients weighing ≥14 kg to <25 kg: 1 tablet containing 30 mg BIC, 120 mg FTC, and 15 mg TAF taken once daily with or without food. For children unable to swallow a whole tablet, the tablet can be split and each part taken separately as long as all parts are ingested within approximately 10 minutes.
- **Renal impairment**: For patients weighing ≥25 kg, not recommended in patients with CrCl 15 to <30 mL/min, or <15 mL/min who are not receiving chronic hemodialysis, or <15 mL/min who are receiving chronic hemodialysis and have no antiretroviral treatment history. For patients weighing ≥14 kg to <25 kg, not recommended in patients with CrCl <30 mL/min.
- **Hepatic impairment**: Not recommended in patients with severe hepatic impairment.
- **Prior to or when initiating**: Test patients for HBV infection.
- **Prior to or when initiating, and during treatment**: As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

Pregnancy and lactation

- **Pregnancy**: BIKTARVY is recommended in pregnant individuals who are virologically suppressed on a stable ARV regimen with no known substitutions associated with resistance to any of the individual components of BIKTARVY. Lower plasma exposures of BIKTARVY were observed during pregnancy; therefore, viral load should be monitored closely during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for BIC, FTC, or TAF show no difference in the rates of birth defects compared with a US reference population.
- **Lactation**: Individuals infected with HIV-1 should be informed of the potential risks of breastfeeding.

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 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.

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 within currently anticipated timelines or at all, and the possibility of unfavorable results from ongoing or additional clinical trials, including those involving Biktarvy, bictegravir, lenacapavir, teropavimab, zinlirvimab and GS-1720 (such as the ALLIANCE, ARTISTRY, BICSTaR, NCT04811040 and NCT05585307 studies); uncertainties relating to regulatory applications and related filing and approval timelines, including potential applications for indications currently under evaluation, 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 programs for indications that are currently under evaluation, including bictegravir, lenacapavir, teropavimab, zinlirvimab and GS-1720, and, as a result, these programs 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 Annual Report on Form 10-K for the year ended December 31, 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 Biktarvy, including Boxed Warning, and U.S. full Prescribing Information for lenacapavir is 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, or contact Gilead Public Affairs at public_affairs@gilead.com, 1-800-GILEAD-5 or 1-650-574-3000.