Biktarvy® Demonstrates High Efficacy and Durable Viral Suppression at Five Years, in Treatment-Naïve Adults

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– Week 240 Results Reinforce the Durability of Biktarvy and Highlight the Potential Role of the Single-Tablet Regimen in Helping to Meet the Long-Term Treatment Needs of a Diverse Group of People Living with HIV –

– Following Five Years of Treatment, Biktarvy Continued to Demonstrate a High Barriere to Resistance with Zero Cases of Treatment Failure Due to Resistance Detected –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 11, 2022-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced the presentation of cumulative 5-year results from two Phase 3 studies (Study 1489 and Study 1490) of Biktarvy® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, B/F/TAF). The new, long-term data further demonstrate the sustained efficacy and safety profile and lack of treatment failure due to resistance in the final resistance analysis population associated with Biktarvy for the treatment of HIV-1 in treatment-naïve adults. The data were presented at the 29th Conference on Retroviruses and Opportunistic Infections (virtual CROI 2022).

In both studies, ≥98% of participants who initiated treatment with Biktarvy and remained in the study for all 240 weeks achieved and maintained an undetectable viral load (HIV-1 RNA <50 copies/mL) through five years of follow-up (Week 240). 1489 n=208/213, 1490: n=218/219, missing equals excluded analysis). Through five years of analysis, zero cases of treatment failure due to emergent resistance were detected among the final resistance analysis population of both studies, further demonstrating the efficacy and tolerability profile of Biktarvy for the treatment of HIV-1 in treatment-naïve adults.

“These latest data presented at CROI help us better understand the role of Biktarvy for long-term treatment and demonstrate its long-term viral suppression and durability,” said David Alain Wohl, MD, Professor of Medicine, Division of Infectious Diseases, the University of North Carolina at Chapel Hill. “Many people living with HIV are concerned about the ability of their therapy to achieve long-term viral suppression since they will likely be on treatment for the duration of their lives. Confidence in the efficacy and robustness of Biktarvy as a complete regimen helps me advance the conversation around what long-term treatment success may look like.”

Data support long-term use of Biktarvy, with no significant changes to metabolic, bone and renal markers. Among study participants, median change in weight from baseline through Week 240 was 6.1 kg, consistent with previously presented data. Study 1489 also demonstrated small impacts on bone mineral density (BMD) outcomes through five years. Mean percentage changes in hip and spine BMD through Week 240 in Biktarvy participants were -0.29% and -0.23%, respectively. In both studies, five participants (n=5/634) experienced a study-drug related adverse event (AE) that led to drug discontinuation. Furthermore, through 240 weeks, numerically small median changes in eGFR and stable TC:HDL ratios were observed in both studies.

“Effective treatment options, such as Biktarvy, are an important tool in addressing the specific needs of certain people living with HIV, including achieving and maintaining an undetectable viral load over the long-term,” said Jared Baeten, MD, PhD, Vice President, HIV Clinical Development, Gilead Sciences. “As we strive to improve HIV treatment and continue to advance scientific innovation, we’re committed to looking beyond viral load suppression to gain a better understanding of how to support the long-term and overall health of people living with HIV. The five-year data presented at CROI are an important step in deepening our understanding of how to tailor our research program to address the individual needs of all people living with HIV, and to help end the global HIV epidemic.”

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

There is currently no cure for HIV or AIDS.

About Studies 1489 and 1490

Study 1489 and Study 1490 are Phase 3, randomized, double-blind, active-controlled studies. For 144 weeks, treatment-naïve participants were blinded to receive either Biktarvy (n=634) or a dolutegravir-containing triple therapy (n=640). The primary endpoint was the proportion of adults with HIV-1 RNA <50 copies/mL at Week 48 using the FDA snapshot algorithm. Secondary endpoints included efficacy, safety, and tolerability assessed through Weeks 96 and 144. Beyond week 144, participants were able to receive Biktarvy in an active open-label extension phase for up to 96 weeks.

About Biktarvy

Biktarvy is a complete HIV-1 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 Descovy® (emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, F/TAF) backbone. Biktarvy is a complete STR and should not be taken with other HIV-1 medicines.

U.S. Indication for Biktarvy

Biktarvy is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 14 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.

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 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**: There is insufficient human data on the use of BIKTARVY during pregnancy. Dolutegravir, another integrase
inhibitor, has been associated with neural tube defects. Discuss the benefit-risk of using BIKTARVY during pregnancy and conception. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for FTC shows no difference in the rates of birth defects compared with a US reference population.

- **Lactation:** Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

### 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 and cancer.

For more than 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention and cure research. Gilead researchers have developed 11 HIV medications, including the first single-tablet regimen to treat HIV and the first antiretroviral for pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV infection. These advances in medical research have helped to transform HIV into a 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 and collaborations, 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 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 or complete clinical trials within currently anticipated timelines or at all, and the possibility of unfavorable results from ongoing and additional clinical trials, including those involving Biktarvy; Gilead’s ability to receive FDA and other regulatory approvals for additional indications for Biktarvy, and the risk that any such approvals, if granted, may have significant limitations on its use; the risk that physicians may not see the benefits of prescribing Biktarvy; 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, 2021, 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 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. Prescribing Information for Biktarvy,** including **BOXED WARNING,** is available at [www.gilead.com](http://www.gilead.com).

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For more information about Gilead, please visit the company’s website at [www.gilead.com](http://www.gilead.com), follow Gilead on Twitter ([@Gilead Sciences](https://twitter.com/GileadSciences)) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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