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For Immediate Release

**GILEAD'S BIKTARVY MAINTAINED HIGH EFFICACY WITH NO CASES OF
TREATMENT-EMERGENT RESISTANCE THROUGH THREE YEARS IN
PHASE 3 HIV CLINICAL TRIALS**

*– Data from the Two 144-week Studies in Treatment-naïve Adults Living with HIV Presented
at European AIDS Conference (EACS)–*

Foster City, Calif. – November 6, 2019 – Gilead Sciences, Inc. (NASDAQ: GILD) today announced findings from two randomized, double-blind, active-controlled Phase 3 studies (Study 1489 and Study 1490) evaluating the safety and efficacy of Biktarvy® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets) compared with dolutegravir (DTG)-containing regimens for the treatment of HIV-1 infection in adults new to HIV therapy. In both studies, Biktarvy was well-tolerated and demonstrated high rates of virologic suppression through Week 144. These data are being presented at the 17th European AIDS Conference (EACS) in Basel, Switzerland.

“The findings presented today support the value of Biktarvy as an effective treatment that offers durable viral suppression and maintains a high barrier to resistance,” said Diana Brainard, MD, Senior Vice President, HIV and Emerging Viruses, Gilead Sciences. “These longer-term data reaffirm Biktarvy’s role as a first-line treatment option for appropriate adults who are living with HIV and are starting therapy.”

Biktarvy is indicated in the United States as a complete regimen for the treatment of HIV-1 infection in patients who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen for at least three months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy. Biktarvy carries a Boxed Warning in its U.S. product label regarding the risk of post-treatment acute exacerbation of hepatitis B. See below for Important Safety Information.

Studies 1489 and 1490 randomized 1,274 treatment-naïve adults to receive Biktarvy or either dolutegravir/abacavir/lamivudine (50/600/300 mg, DTG/ABC/3TC) (Study 1489) or DTG + emtricitabine/tenofovir alafenamide (50/200/25 mg, F/TAF) (Study 1490). The primary endpoint of both studies was virologic suppression, defined as the proportion of participants who were virologically suppressed (HIV-1 RNA levels <50 copies/mL) at Week 48. At the primary endpoint, noninferior efficacy was achieved in both studies and has been previously presented. At Week 144, non-inferiority was maintained from the primary endpoint measurement in both studies at Week 48, with a similar proportion of the Biktarvy group achieving virologic suppression (82 percent; n=518/634) as those taking DTG/ABC/3TC (84 percent; n=265/315) and DTG + F/TAF (84 percent; n=273/325). Across all treatment groups no participants developed treatment failure with treatment-emergent resistance.

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“Developing new HIV treatment regimens that can be used in a wide range of people living with HIV is very important,” said Chloe Orkin, MBBCH, FRCP, Clinical Professor of HIV Medicine at Queen Mary University of London. “The three-year results from both Biktarvy studies provide further evidence that it is potent and effective, enabling people living with HIV to maintain an undetectable viral load over the long term.”

There were no discontinuations due to renal events and no cases of proximal renal tubulopathy or Fanconi syndrome in the Biktarvy treatment group. Similar reductions in median estimated glomerular filtration rate (eGFR) were observed across groups (-9.2 mL/min in patients taking Biktarvy vs. -11.7 mL/min in participants taking ABC/DTG/3TC vs. -11.0 mL/min in participants taking DTG + F/TAF) at Week 144. Study 1489 also assessed other laboratory markers of renal and bone safety in patients taking Biktarvy and DTG/ABC/3TC. Participants in both treatment arms demonstrated similar median changes in proteinuria and mean percentage changes in hip and spine bone mineral density (BMD) from baseline. Small, statistically significant differences in the median change from baseline favoring DTG/ABC/3TC were observed for LDL, HDL and total cholesterol to HDL ratio.

Biktarvy was well tolerated through Week 144. Discontinuations due to adverse events were low across all groups (1 percent (n=6/634) for Biktarvy vs. 2 percent (n=5/315) for DTG/ABC/3TC and 2 percent (n=6/325) for DTG + F/TAF). The proportion of drug-related adverse events (all grades) was 26 percent in the Biktarvy arm (n=165/634) vs. 42 percent (n=132/315) for DTG/ABC/3TC and 29 percent (n=94/325) for DTG + F/TAF). The incidence of drug-related nausea was 4 percent for Biktarvy vs. 18 percent for DTG/ABC/3TC and 5 percent for DTG + F/TAF (p<0.0001 for Biktarvy vs. DTG/ABC/3TC). The most commonly reported treatment-emergent adverse events (all grades) were diarrhea (19 percent for Biktarvy vs. 18 percent for DTG/ABC/3TC and 16 percent for DTG + F/TAF), headache (16 percent for Biktarvy vs. 18 percent for DTG/ABC/3TC and 18 percent for DTG + F/TAF) and nasopharyngitis (14 percent for Biktarvy vs. 17 percent for DTG/ABC/3TC and 19 percent for DTG + F/TAF).

Study 1489 and Study 1490 are ongoing. Beyond Week 144, study participants will have the option to receive Biktarvy in an open-label extension for up to 96 weeks.

Biktarvy does not cure HIV infection or AIDS.

Important U.S. Safety Information and Indication for Biktarvy

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B have been reported in patients who are coinfecting 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 coinfecting 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.

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- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of BIKTARVY, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min. 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 $\geq 5\%$; 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:** Patients weighing ≥ 25 kg: 1 tablet taken once daily with or without food.
- **Renal impairment:** 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.

INDICATION

Biktarvy is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 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 history of treatment failure and no known resistance to any component of Biktarvy.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

For more than 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention, testing and linkage to care, and cure research. Today, it's estimated that more than 12 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company's manufacturing partners.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

Forward-Looking Statement

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 the possibility of unfavorable results from ongoing and additional clinical trials involving Biktarvy. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

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*U.S. full Prescribing Information for Biktarvy, including **BOXED WARNING**, is available at www.gilead.com*

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For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.