Gilead Announces 96-Week Results From Phase 3 Study of Biktarvy® (Bictegravir, Emtricitabine, Tenofovir Alafenamide) for the Treatment of HIV-1 in Adults New to HIV Therapy

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– Biktarvy Showed High Efficacy and High Barrier to Resistance Through 96 Weeks –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 30, 2018-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced 96-week results from a Phase 3, randomized, double-blinded study (Study 1490) evaluating the safety and efficacy of Biktarvy® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, BIC/FTC/TAF) for the treatment of HIV-1 infection in treatment-naïve adults. In the ongoing study, Biktarvy was found to be statistically non-inferior to a regimen of dolutegravir and emtricitabine/tenofovir alafenamide (50 mg) (DTG+FTC/TAF) through 96 weeks of therapy. The data were presented during a late-breaking abstract session at the 2018 HIV Glasgow conference in Glasgow, Scotland, UK.

“This study demonstrated the high efficacy, high barrier to resistance and long-term tolerability profile of Biktarvy through 96 weeks, reaffirming its role as a first-line treatment option for appropriate adult HIV patients who are starting therapy,” said Hans-Jürgen Stellbrink, MD, PhD, Professor of Internal Medicine, Infectious Diseases, at the University of Hamburg, Germany and lead study author. “Biktarvy was also shown to have few discontinuations due to adverse events through 96 weeks, which may be an important consideration for health care providers making clinical care decisions.”

Biktarvy is indicated in the U.S. as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those adults who are virologically suppressed (HIV-1 RNA <50 c/mL) 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.

In Study 1490, treatment-naïve adults (n=645) were randomized 1:1 in a blinded fashion to receive Biktarvy or DTG+FTC/TAF. At Week 96, non-inferiority was maintained from the primary endpoint measurement at Week 48, with 84.1 percent (n=269/320) of patients taking Biktarvy and 86.5 percent (n=281/325) of patients taking DTG+FTC/TAF achieving HIV-1 RNA levels less than 50 copies/mL (difference: -2.3 percent, 95 percent CI: -7.9 percent to 3.2 percent, p=0.41). In the resistance analysis population, none of the study participants randomized to Biktarvy developed treatment-emergent resistance.

Biktarvy was well-tolerated with low discontinuations due to adverse events in both treatment arms (2 percent (n=6) for Biktarvy vs. 2 percent (n=5) for DTG+FTC/TAF [1 Biktarvy and 4 DTG+FTC/TAF after Week 48]). The most commonly reported adverse events (all grades) were diarrhea (18 percent for Biktarvy vs. 16 percent for DTG+FTC/TAF) and headache (16 percent vs. 15 percent). There were fewer treatment-related adverse events (all grades) in the Biktarvy arm compared to DTG+FTC/TAF (20 percent for Biktarvy vs. 28 percent for DTG+FTC/TAF). Lipid changes were not significantly different between the two arms, and there were no renal discontinuations or cases of proximal renal tubulopathy.

“These data presented at HIV Glasgow further demonstrate the efficacy and tolerability profile of Biktarvy, supporting the use of this once-daily single tablet regimen in a broad range of adults living with HIV who are new to HIV therapy,” said John McHutchison, AO, MD, Chief Scientific Officer, Gilead Sciences. “Gilead is working to advance access to Biktarvy to appropriate patients around the world as we continue our clinical and research efforts focusing on novel mechanisms of action for next-generation HIV treatments and, ultimately, a cure.”

Additional clinical trials of Biktarvy are ongoing, including dedicated studies in older adult women, African-American people living with HIV, adolescents and children living with HIV, as well as an additional study in treatment-naïve HIV-1

infected adults (Study 1489). Data from an analysis of pooled treatment-naïve adults in Studies 1489 and 1490 with high viral loads (HIV-1 RNA > 100,000 c/mL) or low CD4 counts (CD4 < 200 cells/µL) are also being presented in a poster session at HIV Glasgow. Biktarvy is only approved for use in adults.

Study 1490 is ongoing and will remain randomized and blinded through 144 weeks.

Biktarvy is approved in Australia, Canada, the European Union, Hong Kong and the United States.

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 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:** 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, also 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 were diarrhea (6%), nausea (5%), 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.

Pregnancy and lactation

- **Pregnancy:** There is insufficient human data on the use of Biktarvy during pregnancy. 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.

Dosage and administration

- **Dosage:** 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.

INDICATION

Biktarvy is indicated as a complete regimen for the treatment of HIV-1 infection in adults 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 for ≥3 months 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 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 risk that physicians may not see the benefits of prescribing Biktarvy for the treatment of HIV-1 infection and the possibility of unfavorable results from additional clinical trials involving Biktarvy. 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 June 30, 2018, 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.

*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.

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