Gilead Presents Results from Phase 3 Study Evaluating Patients Who Switched to Biktarvy® (Bictegravir, Emtricitabine and Tenofovir Alafenamide) from Regimen Containing Abacavir, Dolutegravir and Lamivudine

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-Through 48 Weeks, Biktarvy Found to Be Non-Inferior to Abacavir-Containing Regimen in Virologically Suppressed Adults Living With HIV-

– No Patients in Biktarvy Treatment Arm Demonstrated Treatment-Emergent Resistance Through 48 Weeks –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Mar. 5, 2018-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced detailed 48-week results from a Phase 3 study (Study 1844) evaluating the efficacy and safety of switching from a regimen containing abacavir, dolutegravir and lamivudine (600/50/300mg) (ABC/DTG/3TC) to Biktarvy® (bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg), a once-daily single tablet regimen, in virologically suppressed adults with HIV. Through Week 48, Biktarvy was found to be statistically non-inferior to ABC/DTG/3TC with a numerically lower incidence of mild or moderate study drug-related adverse events and no treatment-emergent resistance. The data were presented at the 2018 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston (Session O-02).

“In this study, Biktarvy maintained high rates of virologic suppression and demonstrated a high barrier to resistance through 48 weeks of treatment, findings that have been consistently observed across all Phase 3 studies of the regimen,” said Jean-Michel Molina, MD, Head of the Infectious Diseases Department, Hospital Saint Louis, Paris, France and lead study investigator. “In addition, people taking Biktarvy experienced fewer drug-related adverse events compared to participants in the comparator arm, a consideration for physicians and their patients who choose to switch HIV treatments.”

Biktarvy is indicated 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 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. No dosage adjustment of Biktarvy is required in patients with estimated creatinine clearance greater than or equal to 30 mL per minute. Biktarvy has a Boxed Warning in its product label regarding the risk of post treatment acute exacerbation of hepatitis B. See below for Important Safety Information.

In Study 1844, a total of 563 virologically suppressed adults with HIV taking a regimen of ABC/DTG/3TC were randomized 1:1 in a blinded fashion to continue a once-daily fixed-dose combination of ABC/DTG/3TC or to switch to Biktarvy. At the primary endpoint of Week 48, switching to Biktarvy was non-inferior to continuing ABC/DTG/3TC with 1.1 percent in the Biktarvy arm and 0.4 percent in the ABC/DTG/3TC arm having HIV-1 RNA ≥50 c/mL (difference: 0.7 percent; 95 percent CI: -1.0 percent to 2.8 percent, p=0.62); the proportion of patients with HIV-1 RNA <50 c/mL was 93.6 percent in the Biktarvy arm and 95.0 percent in the ABC/DTG/3TC arm, according to FDA snapshot algorithm.

Patients in the Biktarvy arm had a lower incidence of study drug-related adverse events than those in the ABC/DTG/3TC arm (8 percent vs. 16 percent, p=0.006; all grades), which were primarily mild or moderate in severity. The difference between groups was primarily driven by numerically more drug-related gastrointestinal (flatulence, nausea, diarrhea) and neuropsychiatric (abnormal dreams and insomnia) adverse events in the ABC/DTG/3TC arm. The most common study drug-related adverse event was headache (3 percent in both arms). Few participants had adverse events leading to premature study discontinuation (2 percent vs. 1 percent).

Through Week 48, no patients in either treatment arm developed treatment-emergent resistance. In addition, there were no renal adverse events leading to discontinuations and no cases of proximal renal tubulopathy in either treatment group. At Week 48, lipid profiles were unchanged after switching to Biktarvy from ABC/DTG/3TC, and bone mineral density

changes from baseline were the same between arms.

“The data presented at CROI this week, in addition to previously reported studies in both treatment-naïve and virologically suppressed adult patients, further demonstrate that Biktarvy may be appropriate for a wide range of people living with HIV who are either new to treatment or who choose to switch regimens,” said Norbert W. Bischofberger, PhD, Gilead’s Executive Vice President, Research and Development and Chief Scientific Officer. “Following the recent approval of Biktarvy in the United States, we look forward to working to expand the availability of this novel therapy to patients around the world.”

Biktarvy was approved by the United States Food and Drug Administration (FDA) on February 7, 2018. A marketing authorization application for Biktarvy is under review in the European Union.

Additional clinical trials of Biktarvy are ongoing, including a dedicated study in women, as well as a study in adolescents and children living with HIV. Data from the women’s study (Study 1961) and a cohort of adolescent subjects enrolled in the pediatric study (Study 1474) are being presented in poster sessions (Posters 2539 and 2271) at CROI.

Biktarvy does not cure HIV infection or AIDS.

Important U.S. 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:** 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.

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.

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.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

For nearly 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 10 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company's manufacturing partners.

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. In addition, the European Union and other regulatory authorities may not approve Biktarvy in the currently anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on their use. 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 Annual Report on Form 10-K for the year ended December 31, 2017, 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.*

Biktarvy is a trademark of Gilead Sciences, Inc., or its related companies.

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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