

Gilead Presents Data From Phase 3 Study Evaluating Women Who Switched to Biktarvy® (Bictegravir, Emtricitabine and Tenofovir Alafenamide) From a Boosted Protease Inhibitor-Based Regimen or Boosted Elvitegravir-Containing Regimen

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– Women in Biktarvy Treatment Arm Maintained High Rates of Virologic Suppression With No Adverse-Event Discontinuations and No Treatment-Emergent Resistance Through 48 Weeks –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Mar. 5, 2018-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced 48-week results from a Phase 3 study (Study 1961) of 470 virologically suppressed adult women with HIV infection, evaluating the efficacy and safety of switching from a boosted protease inhibitor (bPI) or boosted elvitegravir-containing regimen to Biktarvy® (bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg), a once-daily single tablet regimen. In the ongoing study, Biktarvy was found to be statistically non-inferior to regimens containing a bPI or boosted elvitegravir and demonstrated no treatment-emergent resistance at 48 weeks. The data were presented at the International Workshop on HIV and Women and at the 2018 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston (Poster 2539).

“In this study, women who switched to Biktarvy maintained high levels of viral suppression, comparable to those who remained on a baseline regimen of either Genvoya®, Stribild® or ATV+RTV+FTC/TDF, and none of the participants on Biktarvy developed treatment-emergent resistance,” said Cissy Kityo, MD, Deputy Executive Director of Joint Clinical Research Centre, Kampala, Uganda and lead investigator on the study. “Conducting this women-only study on an international scale helps to further demonstrate that Biktarvy may be appropriate for a wide range of people living with HIV.”

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 1961, a total of 470 virologically suppressed adult women taking a regimen of atazanavir (ATV) + ritonavir (RTV) + emtricitabine/tenofovir disoproxil fumarate (FTC/TDF), Stribild (elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/tenofovir disoproxil fumarate 300mg) or Genvoya (elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10mg) were randomized 1:1 to switch to open-label Biktarvy or stay on their baseline regimen (SBR). At Week 48, the primary endpoint of the study, switching to Biktarvy was non-inferior to continuing an SBR with 1.7 percent of participants in both the Biktarvy and the SBR arms having HIV-1 RNA \geq 50 c/mL (difference 0.0 percent; 95 percent CI: -2.9 percent to 2.9 percent, $p=1.00$); the proportion of patients with HIV-1 RNA <50 c/mL was 95.7 percent in the Biktarvy arm and 95.3 percent in the SBR arm, according to FDA snapshot algorithm.

No patients in the Biktarvy treatment arm developed treatment-emergent resistance, while one patient taking Genvoya in the SBR arm developed an emergent M184M/I/V mutation. No renal adverse events leading to discontinuations and no cases of proximal renal tubulopathy occurred in either arm. The most commonly reported adverse events (all grades) in both arms included nasopharyngitis, upper respiratory tract infection, headache, vulvovaginal candidiasis and urinary tract infection. No patient in either treatment group discontinued the study due to an adverse event.

Demographic and baseline characteristics of the study participants were balanced with 37 percent Black, 28 percent white, 22 percent Asian and 16 percent Hispanic or Latina, a median age of 39 years and a median CD4 count of 686 cells/ μ L. Participants were recruited in the Dominican Republic, Russia, Thailand, Uganda and the United States.

“Gilead is committed to researching and developing treatments that have the potential to be used in a broad range of patients, including women who have traditionally been underrepresented in HIV clinical trials,” said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. “This study demonstrates that Biktarvy offers a safety and efficacy profile that may help to care for women living with HIV.”

Additional clinical trials of Biktarvy are ongoing, including a study in adolescents and children living with HIV. Biktarvy is only approved for use in adults.

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.

Biktarvy does not cure HIV infection or AIDS.

Further information about the clinical study can be found at www.clinicaltrials.gov.

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 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.
- **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 $\geq 5\%$; 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. 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, Stribild and Genvoya, including **BOXED WARNINGS**, are available at www.gilead.com.

Biktarvy, Stribild and Genvoya are trademarks 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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