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

October 3, 2018 8:31 AM ET

– Biktarvy Showed High Efficacy and a Demonstrated Tolerability Profile Through 96 Weeks –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 3, 2018-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced 96-week results from a Phase 3, randomized, double-blinded study (Study 1489) evaluating the safety and efficacy of Biktarvy® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets) 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 abacavir/dolutegravir/lamivudine (600/50/300mg, ABC/DTG/3TC) through 96 weeks of therapy. The data will be presented during a late-breaking abstract session at the IDWeek 2018 conference in San Francisco.

“Healthcare providers who care for people living with HIV are always seeking treatment options that offer high efficacy, a high barrier to treatment-emergent resistance and a long-term tolerability profile,” said David Wohl, MD, Professor of Medicine, Division of Infectious Diseases, the University of North Carolina at Chapel Hill and lead study author. “This study underscores the role of Biktarvy as a first-line treatment option for appropriate adults living with HIV who are new to therapy. In addition, Biktarvy was shown to have less nausea with a similar bone and renal safety profile to the comparator through 96 weeks.”

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. No dosage adjustment of Biktarvy is required in adult patients with estimated creatinine clearance greater than or equal to 30 mL per minute. 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 1489, treatment-naïve adults (n=629) were randomized 1:1 in a blinded fashion to receive Biktarvy (BIC/FTC/TAF) or ABC/DTG/3TC. At Week 96, non-inferiority was maintained from the primary endpoint measurement at Week 48, with 87.9 percent (n=276/314) of patients taking Biktarvy and 89.8 percent (n=283/315) of patients taking ABC/DTG/3TC achieving HIV-1 RNA levels less than 50 copies/mL (difference: -1.9 percent, 95 percent CI: -6.9 percent to 3.1 percent, p=0.45). In the resistance analysis population, none of the study participants randomized to Biktarvy developed treatment-emergent resistance.

There were no renal discontinuations and no cases of proximal renal tubulopathy or Fanconi syndrome in the Biktarvy treatment group. The median change in estimated glomerular filtration rate (eGFR) from baseline to Week 96 was significantly less with Biktarvy compared with ABC/DTG/3TC (-7.8 mL/min vs. -9.6 mL/min, p=0.01). Median changes in proteinuria were similar between both treatment groups. Additionally, the mean percent changes from baseline in spine and hip bone mineral density in the Biktarvy group were similar to ABC/DTG/3TC group (spine: -0.71 vs. -0.22, p=0.14; hip: -1.13 vs. -1.26, p=0.59).

Biktarvy was well tolerated through Week 96. Discontinuations due to adverse events were low in both groups (0.0 percent (n=0) for Biktarvy vs. 2 percent (n=5) for ABC/DTG/3TC). The most commonly reported adverse events (all grades) were nausea (11 percent for Biktarvy vs. 24 percent for ABC/DTG/3TC), diarrhea (15 percent vs. 16 percent) and headache (13 percent vs. 16 percent).

“Gilead is committed to developing innovative treatments like Biktarvy that help address the unmet needs of people living with HIV,” said John McHutchison, AO, MD, Chief Scientific Officer, Gilead Sciences. “This study further supports the efficacy and resistance profiles of Biktarvy through 96 weeks. We look forward to presenting additional data that

demonstrate the long-term utility of Biktarvy at upcoming scientific conferences."

Study 1489 is ongoing and will remain randomized and blinded through 144 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 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*

Biktarvy, Gilead and the Gilead logo 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20181003005315/en/

Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Investors
Sung Lee, (650) 524-7792
or
Media
Ryan McKeel, (650) 377-3548