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Gilead Presents Real-World Evidence Reinforcing the Use of Biktarvy® for the Treatment of People Living With HIV With a Range of Comorbidities

– New Clinical Outcomes from BICSTaR Study Show Sustained Impact of Biktarvy for People with HIV –

– Five-Year Data from Studies 1489 and 1490 Solidify the Robust and Durable Efficacy and Safety Profile of Biktarvy –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced the presentation of real-world results from the BICSTaR study, highlighting Biktarvy® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, B/F/TAF) as a generally well tolerated and efficacious regimen regardless of prior treatment and comorbidity status in people with HIV. The latest five-year data from two Phase 3 studies (Study 1489 and Study 1490) provide evidence of the long-term safety and efficacy profile of Biktarvy in those who switch from a dolutegravir-containing regimen. The data were presented at the 30th International Congress on Drug Therapy in HIV Infection (HIV Glasgow 2022).

New real-world data was presented from the 24-month BICSTaR follow-up analysis, evaluating the effectiveness and safety of Biktarvy in clinical practice across nine countries. The analysis included follow-up during the COVID-19 pandemic and considered age, race, sex, adherence, and late diagnosis in the population group. Trial participants who initiated treatment with Biktarvy experienced high viral suppression (HIV-1 RNA <50 copies/mL). Overall, 97% (104/107) of treatment-naïve and 95% (497/521) of treatment-experienced participants achieved viral suppression (missing=excluded analysis) at 24 months. There were no reports of treatment-emergent resistance. Treatment discontinuations (14% overall) were low, and few people (7%) discontinued Biktarvy as a result of drug-related AEs (DRAEs). The most commonly reported drug-related adverse events were weight change (3%) and depression (1%). These data reinforce the safety and durability of Biktarvy for people with HIV with a high level of comorbidities.

“These latest data demonstrate how innovation and improvement in HIV treatment options can help people living with HIV and their clinicians identify an HIV treatment regimen that supports their treatment over the long-term,” said Benoit Trottier, MD, Physician and Director of Research at Clinique de Médecine Urbaine du Quartier Latin,

Montreal, Canada. “Factors such as aging and comorbidities are vital components of long-term health discussions. The BICSTaR study reinforces the real-world effectiveness of Biktarvy across populations with a range of comorbidities and the findings are consistent with evidence from randomized clinical trials of Biktarvy treatment.”

Additional data from Study 1489 and Study 1490 presented at the conference show Biktarvy to have high efficacy and sustained safety for people switching to the treatment, with a continued high barrier to resistance. These outcomes were reported in participants 96 weeks after switching to open-label Biktarvy following 144 weeks of blinded dolutegravir + 2 NRTIs. At Week 240, more than 99% of participants in both Study 1489 (217/218; missing=excluded) and Study 1490 (232/234; missing=excluded) achieved viral suppression. Additionally, at every visit through 240 weeks, the study showed that following the switch to Biktarvy, efficacy was >96% (missing=excluded), demonstrating that Biktarvy may provide sustained viral suppression for people with HIV, even after switching treatments. Biktarvy was generally well tolerated, with 0.4% (2/519) of switch participants in both studies experiencing an AE that led to drug discontinuation in the open-label extension period. There were no renal discontinuations. The most commonly reported adverse events during the open-label extension phase were diarrhea (0.6%) and weight change (0.6%).

On October 14, 2022, the U.S. Food and Drug Administration (FDA) approved a label change for Biktarvy, updating the prescribing information to include efficacy data from 144 weeks and safety data from 240 weeks of clinical trial data in adults with HIV who were initiating therapy in Study 1489 and Study 1490.

“As we strive to advance scientific innovation with the goal of helping to end the HIV epidemic, we’re committed to a treatment research program that addresses the individual needs of all people with HIV,” said Jared Baeten, MD, PhD, Vice President, HIV Clinical Development, Gilead Sciences. “Gilead’s ongoing, person-centered research is focused on the evolving needs and preferences of people living with HIV. These latest data presented at HIV Glasgow 2022 demonstrate the clinical use of innovative medicines like Biktarvy to help a broad range of people with HIV, regardless of their burden of comorbidities.”

Please see below for the U.S. Indication and Important Safety Information, including Boxed Warning, for Biktarvy.

There is currently no cure for HIV or AIDS.

About the BICSTaR Study

The Bictegravir Single Tablet Regimen (BICSTaR) study is an ongoing, multinational, observational single-arm, non-comparative real-world cohort study, which aims to evaluate the effectiveness, safety, tolerability, and patient-reported outcomes of treatment with Biktarvy in treatment-naïve and treatment-experienced people with HIV. Among the people with HIV enrolled in the BICSTaR study, there is a high baseline prevalence of comorbidities.

About Studies 1489 and 1490

Study 1489 and Study 1490 are Phase 3, randomized, double-blind, active-controlled studies. For 144 weeks, treatment-naïve participants were blinded to receive either Biktarvy (n=634) or a dolutegravir-containing triple therapy (n=640). The primary endpoint was the proportion of adults with HIV-1 RNA <50 copies/mL at Week 48 using the FDA snapshot algorithm. Secondary endpoints included efficacy, safety, and tolerability assessed through Weeks 96 and 144. Beyond week 144, participants were given the option to receive Biktarvy in an active open-label extension phase for up to 96 weeks.

About Biktarvy

Biktarvy is a complete HIV treatment that combines three powerful medicines to form the smallest 3-drug, integrase strand transfer inhibitor (INSTI)-based single-tablet regimen (STR) available, offering simple once-daily dosing with or without food, with a limited drug interaction potential and a high barrier to resistance. Biktarvy combines the novel, unboosted INSTI bictegravir, with the Descovy® (emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, F/TAF) backbone. Biktarvy is a complete STR and should not be taken with other HIV medicines.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.