New Data on Gilead's Biktarvy® Presented at CROI 2020, Including Data in Black Americans and Older Adults

March 9, 2020

– Phase 3 Data from the BRAAVE 2020 Study in Black or African American Virologically Suppressed Adults Presented, Including Patients with a History of Treatment Failure or Pre-Existing Resistance –

– Analysis of Separate Studies Shows Biktarvy is Effective and Well-Tolerated in Treatment-Naïve Adults 50 and Older, with No Significant Differences in Bone Density, Kidney Safety or Weight Over Three Years –

BOSTON--(BUSINESS WIRE)--

Gilead Sciences Inc. (Nasdaq: GILD) today announced data from the BRAAVE 2020 study, a Phase 3 clinical trial evaluating the safety and efficacy of switching to Biktarvy® (bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets, BIC/FTC/TAF) in virologically suppressed adults living with HIV who self-identified as Black or African American. The data show that, at 24 weeks, switching to Biktarvy from a standard regimen of two nucleoside reverse transcriptase inhibitors (NRTIs) plus a third agent may potentially be an effective and well-tolerated treatment regimen in patients with a history of treatment failure or pre-existing resistance, and did not result in treatment emergent resistance to study drugs with Biktarvy. The use of Biktarvy in individuals with a history of treatment failure or known resistance to the components of Biktarvy is investigational.

"As an African American I have experienced the impact of HIV in my community, family and friends. Importantly, as a front-line doctor treating a high percentage of persons of color with HIV, I am keenly aware of race-specific complications affecting Black Americans with HIV. However, less is known of the impact that race has on the efficacy and side effects of HIV medications," said Debbie P. Hagins, MD, Medical Director, CARE Centers of Coastal Georgia, APCRF, Coastal Health District, Savannah, GA and principal investigator for the BRAAVE 2020 study. "BRAAVE 2020 is a landmark HIV treatment study, investigating the specific treatment responses of Black and African Americans, who experience the highest rates of HIV in the United States. These findings from the BRAAVE study provide further evidence of Biktarvy's role as an effective and well-tolerated treatment option for Black Americans living with HIV and supports further study in people living with HIV who have certain pre-existing drug resistance."

Biktarvy is indicated in the U.S. as a complete regimen for the treatment of HIV-1 infection in adults or pediatric patients weighing at least 25 kg who have no antiretroviral treatment history. While it is also indicated for treatment experienced adults and pediatric patients weighing at least 25 kg who are virologically suppressed and on a stable antiretroviral regimen, these patients must have no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.

On June 18, 2019, the U.S. Food and Drug Administration (FDA) approved the supplemental indication for including pediatric patients weighing at least 25 kg, an important milestone for Biktarvy and Gilead's HIV treatment portfolio.

Gilead also announced results of a pooled analysis from two Phase 3 studies showing Biktarvy continued to be highly effective and well-tolerated in treatment-naïve patients age 50 and older over three years of treatment. Importantly, participants experienced no clinically significant differences in key measures such as bone density, renal laboratory markers or weight. These data from the two 144-week studies in treatment-naïve adults living with HIV will be presented at CROI 2020, in addition to results from an investigational study evaluating the efficacy, safety and pharmacokinetics of low-dose Biktarvy in pediatric patients.

"These data affirm once-daily Biktarvy as an effective choice for appropriate people switching treatment regimens, and as a well-tolerated first-line option that enables people over 50 living with HIV to sustain an undetectable viral load over the long-term," said Diana Brainard, MD, Senior Vice President, HIV and Emerging Viruses, Gilead Sciences. "The data presented at CROI 2020 are part of our relentless pursuit to address unmet needs in HIV treatment. The results underscore the ability of Biktarvy to meet the specific treatment needs of diverse groups of people living with HIV today, including men and women aging with HIV."

Key abstracts for Biktarvy data presented at CROI 2020 include:

Oral 2979: Randomized Switch To B/F/TAF In African American Adults with HIV

In the BRAAVE 2020 study, adults (495) who self-identified as Black or African American and were virologically-suppressed on a baseline regimen of two NRTIs plus a third agent, were randomized 2:1 to switch to open-label Biktarvy once-daily or to stay on their baseline regimen. Study participants with prior treatment failure and pre-existing NNRTI, PI and/or NRTI resistance were eligible to enroll. People living with HIV with resistance to tenofovir (K65R/E/N, ≥3 thymidine analogue mutations or T69-insertions), primary INSTI-resistance, or a history of failure on an INSTI-based regimen were excluded. 32 percent of evaluable patients were cisgender women and 2 percent were transgender women. The primary endpoint of the study was noninferior virologic response (HIV-1 RNA ≥ 50 c/mL) at Week 24. The secondary endpoint was a change from baseline in CD4 count.

The study showed noninferior antiviral efficacy for people switching to Biktarvy from a variety of regimens, including in patients with pre-existing NRTI resistance. At Week 24, 96.3 percent of study participants treated with Biktarvy and 94.5 percent of study participants who stayed on their baseline regimen maintained viral suppression, with no treatment-emergent resistance detected. The most common adverse events (AEs) in the study were headache, diarrhea and insomnia. Most treatment-related AEs were grade 1. AEs leading to study drug discontinuation occurred in 1.8 percent of patients receiving Biktarvy and 0 percent remaining on their baseline regimen.

In the United States, the use of Biktarvy in patients with a history of treatment failure or known resistance to any components of Biktarvy is investigational and the safety and efficacy of this use has not been determined.

Poster 2886: 144-Week Efficacy and Safety Of B/F/TAF In Treatment-Naive Adults ≥50 Yrs

The double-blind Phase 3 studies 1489 and 1490 randomized 1274 treatment-naïve adults to assess the safety and efficacy of Biktarvy. Study 1489

evaluated Biktarvy compared to dolutegravir, abacavir, and lamivudine (DTG/ABC/3TC), and study 1490 compared Biktarvy to DTG + F/TAF. Study 1489 also observed proteinuria and bone mineral density (BMD). A pooled analysis of these studies assessed efficacy, defined as the proportion of participants maintaining viral suppression (HIV-1 RNA <50 c/mL), and adverse events (AEs) at 144 weeks in participants age 50 and older and in participants who were younger than 50 when they entered the study. Across the studies, 196 participants (N=96, 41, and 59, in the Biktarvy, DTG/ABC/3TC, and DTG+FTC/TAF groups, respectively) were age 50 or older; 17 percent of these were women, 27 percent were Black, and 15 percent were of Latino/Hispanic ethnicity.

At Week 144, Biktarvy was found to be highly effective and well-tolerated in adults age 50 or older, with no clinically significant differences in bone density or renal safety, fasting lipids or weight gain from baseline. Across treatment groups, the most common adverse events in patients age 50 and older were nasopharyngitis, diarrhea and upper respiratory tract infection, and most treatment-related AEs were grade 1. AEs leading to study drug discontinuation for participants age 50 and older occurred in 2 percent of patients receiving Biktarvy, compared to 5 percent receiving DTG/ABC/3TC and 7 percent receiving DTG + F/TAF. In Study 1489, mean percent changes in hip and spine bone mineral density (BMD), proteinuria, and renal biomarkers were similar between the Biktarvy and DTG/ABC/3TC treatment groups. Small changes from baseline were observed in all treatment groups in fasting lipids. Median weight increased from baseline at Week 144, with no significant difference between treatment groups (4.3 kg, 4.7 kg, and 3.4 kg, in the Biktarvy, DTG/ABC/3TC, and DTG+FTC/TAF groups, respectively.

Study 1489 and Study 1490 are ongoing. Beyond Week 144, study participants will have the option to receive Biktarvy in an open-label extension for up to 96 weeks.

Gilead will also present additional Biktarvy clinical development program data on March 10, including **Poster 3929: Safety, PK, and Efficacy of Low Dose B/F/TAF in Children ≥2 Years Old Living With HIV.** In the United States, Biktarvy (50/200/25 mg) is currently approved for pediatric patients who weigh at least 25 kg. The low dose of Biktarvy (30/120/15 mg) used in this study and the use in patients who weigh less than 25 kg are investigational and the safety and efficacy have not been determined.

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, 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 through week 144 were diarrhea (6%), nausea (6%), 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:** Patients weighing ≥25 kg: 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. Dolutegravir, another integrase inhibitor, has been associated with neural tube defects. Discuss the benefit-risk of using BIKTARVY during pregnancy and conception. 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.

INDICATION

Biktarvy is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg 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 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 than 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 12 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 possibility of unfavorable results from ongoing and additional clinical trials involving Biktarvy, and the possibility that we are unable to complete one or more of such trials on the currently anticipated timelines or at all. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. 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, 2019, 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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