U.S. FOOD AND DRUG ADMINISTRATION APPROVES EXPANDED INDICATION OF GILEAD'S BIKTARVY® FOR TREATMENT OF HIV-1 IN PEDIATRIC POPULATIONS

– Biktarvy Provides an Effective Treatment Option for a Diverse Range of People Living with HIV, including Children –

Foster City, Calif., October 18, 2021 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced the U.S. Food and Drug Administration (FDA) approved a new low-dose tablet dosage form of Biktarvy® (bictegravir 30 mg/emtricitabine 120 mg/tenofovir alafenamide 15 mg tablets) for pediatric patients weighing at least 14 kg to less than 25 kg who are virologically suppressed or new to antiretroviral therapy. The approval of this supplemental New Drug Application (sNDA) expands the indication for Biktarvy to include younger children living with HIV-1 infection and will help to close the gap between HIV treatment options available for adults and children.

"Children living with HIV are in need of effective and accessible formulations of antiretroviral therapy," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "To address this unmet need, innovations in pediatric formulations must strive towards expanding treatment options for children. The sNDA approval is an important step in fulfilling Gilead's commitment to a goal of bringing pediatric formulations of Biktarvy to children living with HIV around the world."

While effective available treatment options for pregnant women living with HIV lower the likelihood of perinatal HIV infection transmission, pediatric HIV remains a global health problem. Each day in 2020, approximately 850 children worldwide became infected with HIV and approximately 330 children died from AIDS-related causes, mostly because of inadequate access to HIV care and treatment services. The availability of a single-tablet antiretroviral regimen for children weighing at least 14 kg is a significant milestone with the potential to save many lives.

"As children living with HIV will be on therapy for the foreseeable future and from such a young age, there are a number of factors I weigh as a clinician when prescribing the right HIV treatment option to my pediatric patients," said Carina Rodriguez, MD, Professor of Pediatrics and Division Chief of Pediatric Infectious Diseases at the University of South Florida Morsani College of Medicine. "Finding an efficacious treatment option is paramount, but tolerability and safety are keys to ensuring treatment success. With this expanded approval, clinicians can add Biktarvy to their arsenal of options to help ensure these children maintain virologic suppression with a treatment option that makes sense for them."

In the United States, Biktarvy is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.

The approval of Biktarvy for children weighing at least 14 kg is based on data from Cohort 3 of a Phase 2/3 open-label, single-arm study (NCT02881320), which found Biktarvy low-dose tablets to be effective and generally well-tolerated through 24 weeks in virologically suppressed children living with HIV-1. Cohort 3 enrolled 22 participants weighing ≥14 to <25 kg who continued on treatment for 48 weeks and could then continue to receive study drug through an extension phase. After switching to Biktarvy, 91% (20/22) of participants remained virologically suppressed at Week 24, and the mean change in CD4 %

from baseline was 0.2%. HIV-1 RNA was not collected at Week 24 for two participants because of COVID-19 pandemic-related study disruption. In pediatric studies, no new adverse reactions or laboratory abnormalities were identified compared to those observed in adults.

Biktarvy does not cure HIV or AIDS.

About Pediatric HIV

While there have been many advances in the treatment of HIV in children and adolescents, there still remains a need to prioritize, evaluate and develop options for the nearly 3 million children worldwide under the age of 19 living with HIV. An estimated 120,000 children and adolescents died from AIDS-related causes in 2020. About 72 percent of these mostly preventable deaths occurred among children under 10 years old. Newer, child-friendly formulations with appropriate dosing for children and adolescents represent an unmet need that is an important part of the considerations associated with long-term health and wellness for people who will live with HIV for their entire lives until we find a cure. Gilead has partnered with a number of global organizations and initiatives to ensure that we are optimizing and closing treatment gaps for children and adolescents in need so that ultimately, we can end the epidemic.

About Biktarvy

Biktarvy is a complete HIV-1 treatment that combines 3 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 single-tablet regimen and should not be taken with other HIV-1 medicines.

In February 2018, the U.S. FDA approved Biktarvy (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, B/F/TAF) as a once-daily single-tablet regimen for the treatment of HIV-1 infection in adults. In June 2019, the FDA approved labeling revisions to Biktarvy, expanding the patient population to include pediatric patients weighing at least 25 kg. In October 2021, the FDA approved a new low-dose tablet formulation of Biktarvy (bictegravir 30 mg/emtricitabine 120 mg/tenofovir alafenamide 15 mg tablets) for pediatric patients weighing at least 14 kg to less than 25 kg. For all patient populations, Biktarvy is only indicated for the treatment of HIV-1 infection in people who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.