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European Commission Grants Expanded Marketing Authorization for Gilead's Biktarvy® for the Treatment of HIV in Pediatric Populations

– EC Authorizes a Low-Dose Tablet for HIV Treatment in Virologically Suppressed Children at Least Two Years of Age and Weighing at Least 14 kg, Helping to Address a Critical Unmet Need –

– Biktarvy Provides an Effective Therapy Choice for a Diverse Range of People Living with HIV, including Children with Limited Treatment Options –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Commission (EC) has authorized a new low-dose tablet dosage form of Biktarvy® (bictegravir 30 mg/emtricitabine 120 mg/tenofovir alafenamide 15 mg tablets) and an extension of the indication for Biktarvy to treat HIV infection in virologically suppressed children who are at least two years of age and weigh at least 14 kg. The European Marketing Authorization is the first pediatric approval for Biktarvy in the European Union (EU) and applies to all 27 member states of the EU, as well as Norway, Iceland and Liechtenstein.

"The European Commission's approval is a significant milestone to address what is sadly an important unmet need, namely children with HIV requiring new treatment options," said Jared Baeten, MD, PhD, Vice President, HIV Clinical Development, Gilead Sciences. "Additional therapy choices help to ensure children can access care and expand their HIV treatment options, which helps advance the collective efforts to overcome the HIV epidemic. Through the Gilead Global Pediatric Center of Excellence, we are committed to applying our decades of antiviral expertise to drive innovation in pediatric HIV research."

While there have been many advances in the treatment of HIV in children and adolescents, there remains a need to prioritize, evaluate and develop options for the millions of the children worldwide. In 2021, an estimated 800,000 children under the age of 19 living with HIV were still not receiving HIV treatment. Children comprised 4% of people with HIV in 2021 but 15% of AIDS-related deaths, and the gap in HIV treatment coverage between children and adults is increasing rather than narrowing.

The authorization of an extended indication and line extension for Biktarvy for the treatment of HIV in children at least two years of age and weighing at least 14 kg is based on an open-label study (NCT02881320), which found Biktarvy to be effective and generally well-tolerated through 24 weeks in virologically suppressed adolescents and children with HIV. In Study 1474, treatment outcomes with Biktarvy were evaluated in virologically suppressed adolescents between the ages of 12 to less than 18 years weighing at least 35 kg (treatment cohort 1, N=50) and in virologically suppressed children between the ages of 6 to less than 12 years weighing at least 25 kg (treatment cohort 2, N=50). Treatment outcomes with Biktarvy were also evaluated in virologically suppressed children at least 2 years of age and weighing at least 14 kg to less than 25 kg (treatment cohort 3, N=22). At Week 2 or Week 4, select study participants from the three treatment cohorts underwent an intensive pharmacokinetic (PK) evaluation to confirm the dose to be administered in each treatment cohort. All participants from the three treatment cohorts went on to receive Biktarvy for 48 weeks. Beyond Week 48, participants can receive Biktarvy in an active open-label extension phase for up to 96 weeks.

After switching to Biktarvy, 98% (49/50) of participants in treatment cohort 1 remained suppressed (HIV-1 RNA < 50 copies/mL) at Week 48. After switching to Biktarvy, 98% (49/50) of participants in treatment cohort 2 remained suppressed (HIV-1 RNA < 50 copies/mL) at Week 48. After switching to Biktarvy, 91% (20/22) of participants in treatment cohort 3 remained virologically suppressed at Week 24. In this study, no new adverse reactions have been observed in pediatric subjects aged 2 years and older living with HIV-1 as compared to those observed in adults.

Biktarvy is indicated in the EU for the treatment of HIV infection in adults and paediatric patients at least 2 years of age and weighing at least 14 kg without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir. For important safety information for Biktarvy, including dosing and method of administration, special warnings, drug interactions and adverse drug reactions, please see the Summary of Product Characteristics (SmPC) for Biktarvy, available from the European Medicines Agency website at www.ema.europa.eu.

Biktarvy does not cure HIV or AIDS.

About Pediatric HIV

Each day in 2021 approximately 850 children became infected with HIV and approximately 301 children died from AIDS related causes, mainly due to inadequate access to HIV care and treatment services. About 72 percent of these mostly preventable deaths occurred among children under 10 years old. Newer 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 live with HIV. Gilead has partnered with several 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 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.