European CHMP Adopts Positive Opinion for Gilead's Biktarvy® (Bictegravir, Emtricitabine, Tenofovir Alafenamide)

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– In Clinical Trials, Biktarvy Demonstrated High Efficacy and Zero Resistance Through 48 Weeks –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 27, 2018-- Gilead Sciences, Inc. (NASDAQ:GILD) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has adopted a positive opinion on the company's Marketing Authorization Application (MAA) for Biktarvy® (bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg; BIC/FTC/TAF), a once-daily single tablet regimen (STR) for the treatment of HIV-1 infection in adults without present or past evidence of viral resistance to the integrase class, emtricitabine or tenofovir.

BIC/FTC/TAF combines the potency of the novel integrase strand transfer inhibitor (INSTI) bictegravir, with the demonstrated safety and efficacy profile of the Descovy® (emtricitabine 200 mg/tenofovir alafenamide 25 mg; FTC/TAF) dual nucleoside reverse transcriptase inhibitor (NRTI) backbone.

"Triple therapy has been the standard of HIV treatment for more than 20 years and has allowed people living with HIV to achieve durable undetectability. At Gilead, we have continued to explore ways to improve and provide more HIV treatment options, with the goal of going beyond reducing viral load and helping to address some of the wider challenges faced by people living with HIV," said Andrew Cheng, MD, PhD, Chief Medical Officer, Gilead Sciences. "If approved, Biktarvy would be the fifth TAF-based product for HIV in the European Union in the past three years, and because of its drug interaction profile, minimal monitoring requirements and ease of administration we believe it could represent a meaningful advance in HIV treatment for appropriate patients in Europe."

The MAA for BIC/FTC/TAF is supported by data from four ongoing Phase 3 studies: Studies 1489 and 1490 in treatment-naïve HIV-1 infected adults, and Studies 1844 and 1878 in virologically suppressed adults. The trials are comprised of a population of 2,415 participants. BIC/FTC/TAF met its primary objective of non-inferiority at 48 weeks in all four studies.

The CHMP's recommendation will now be reviewed by the European Commission, which has the authority to approve medicines for use in the 28 countries of the European Union, Norway, Iceland and Liechtenstein. A European Commission decision is expected in mid-2018.

BIC/FTC/TAF was approved by the U.S. Food and Drug Administration (FDA) on February 7, 2018.

In the European Union, BIC/FTC/TAF is an investigational product and its efficacy and safety have not yet been established.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

For nearly 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention and cure research. Today, it's estimated that more than 10 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company's generic 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 risk that the European Commission may not approve BIC/FTC/TAF in the currently anticipated timelines or at all, and any marketing approval, if granted, may have significant limitations on its use. 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, 2017, 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.

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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Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Investors
Sung Lee, 650-524-7792
or
Media
Ryan McKeel, 650-377-3548
or
Media (EU)
Stephen Head, +44 (0)7768 705945