Gilead Announces U.S. FDA Priority Review Designation for Fixed-Dose Combination of Bictegravir, Emtricitabine and Tenofovir Alafenamide for Treatment of HIV

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-- Final FDA Decision Anticipated by February 12, 2018 --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Aug. 10, 2017-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has granted priority review for the company's New Drug Application (NDA) for an investigational, fixed-dose combination of bictegravir (50mg) (BIC), a novel investigational integrase strand transfer inhibitor (INSTI), and emtricitabine/tenofovir alafenamide (200/25mg) (FTC/TAF), a dual-NRTI backbone, for the treatment of HIV-1 infection. Gilead filed the NDA for BIC/FTC/TAF with a Priority Review voucher on June 12, 2017, and FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of February 12, 2018.

The NDA is supported by data from four Phase 3 studies that evaluated the fixed-dose combination among treatment-naïve patients and among virologically suppressed patients. A marketing application for BIC/FTC/TAF is also under review in the European Union, and was validated by the European Medicines Agency (EMA) in July. Bictegravir in combination with FTC/TAF as a single tablet regimen is an investigational treatment that has not been determined to be safe or efficacious and is not approved anywhere globally.

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 30 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, testing and linkage to care, 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 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 that FDA and other regulatory authorities may not approve BIC/FTC/TAF in the currently anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on their use. As a result, BIC/FTC/TAF may never be successfully commercialized. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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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