European Medicines Agency Validates Gilead's Marketing Application for Fixed-Dose Combination of Bictegravir, Emtricitabine and Tenofovir Alafenamide for Treatment of HIV

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– EMA MAA Validation Follows Submission of NDA for BIC/FTC/TAF to the U.S. FDA –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 13, 2017-- Gilead Sciences, Inc. (NASDAQ:GILD) today announced that the company's Marketing Authorization Application (MAA) for an investigational, once-daily single tablet regimen containing bictegravir (50 mg; BIC), a novel investigational integrase strand transfer inhibitor (INSTI), and emtricitabine/tenofovir alafenamide (200/25mg; FTC/TAF) for the treatment of HIV-1 infection in adults has been fully validated and is now under evaluation by the European Medicines Agency (EMA).

BIC/FTC/TAF has demonstrated high rates of virologic suppression and no treatment-emergent resistance through 48 weeks in Phase 3 clinical trials among treatment-naïve adult patients and among virologically suppressed adult patients who switched regimens.

"This investigational single tablet regimen represents a potential advance in HIV treatment by combining the potency of an integrase inhibitor, bictegravir, with the demonstrated safety profile of the FTC/TAF backbone," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Gilead remains at the forefront of driving innovation in HIV, with our continued commitment to working to simplify and improve treatments for people living with HIV."

The MAA for BIC/FTC/TAF is supported by data from four Phase 3 studies in which the regimen met its primary objective of non-inferiority at 48 weeks. Three of the ongoing studies are designed to explore the efficacy and safety of BIC/FTC/TAF compared to triple-therapy regimens containing dolutegravir (50mg; DTG); two in treatment-naïve patients and one in virologically suppressed patients (HIV-1 RNA levels <50 copies/mL) switching from an existing DTG-containing antiretroviral regimen. A fourth ongoing study in virologically suppressed patients compares switching to BIC/FTC/TAF versus remaining on a suppressive regimen of two nucleoside/nucleotide reverse transcriptase inhibitors and a boosted protease inhibitor.

The BIC/FTC/TAF filing will be reviewed by the EMA under the centralized licensing procedure for all 28 member states of the European Union, as well as Norway and Iceland.

Gilead submitted a New Drug Application (NDA) for BIC/FTC/TAF in the United States on June 12, 2017, and 48-week data from two Phase 3 studies investigating BIC/FTC/TAF compared to regimens containing DTG in treatment-naïve adult patients will be presented at the International AIDS Society Conference on HIV Science (IAS 2017), July 23-26, 2017, in Paris.

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 EMA and other regulatory agencies may not approve BIC/FTC/TAF, and any marketing approvals, 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 Quarterly Report on Form 10-Q for the quarter ended March 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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