Gilead Submits New Drug Application to U.S. Food and Drug Administration for Fixed-Dose Combination of Bictegravir, Emtricitabine and Tenofovir Alafenamide for HIV Treatment

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– Investigational Single Tablet Regimen May Have Potential to Advance Triple-therapy HIV Treatment for a Broad Range of Patients –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jun. 12, 2017-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for an investigational, once-daily single tablet regimen containing bictegravir (50 mg) (BIC), a novel investigational integrase strand transfer inhibitor, and emtricitabine/tenofovir alafenamide (200/25 mg) (FTC/TAF) for the treatment of HIV-1 infection in adults. 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.

“We aim to simplify the management of HIV for a broad range of patients with this single tablet regimen that combines the potency of an integrase inhibitor, bictegravir, and the demonstrated long-term safety profile of the FTC/TAF backbone,” said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. “This regulatory filing is a demonstration of Gilead’s ongoing commitment to bringing forward treatment innovations that have the potential to address the needs of patients and physicians.”

The NDA for BIC/FTC/TAF is supported by data from four Phase 3 studies in which the regimen met its primary objective of non-inferiority. 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) among treatment-naïve patients and among virologically suppressed patients (HIV-1 RNA levels <50 copies/mL) switching from an existing antiretroviral regimen with dolutegravir. 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.

Gilead plans to submit a marketing authorization application for BIC/FTC/TAF in the European Union in the third quarter of 2017.

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 FDA and other regulatory agencies may not approve BIC/FTC/TAF, and any marketing approvals, if granted, may have significant limitations on its use. In addition, there are risks associated with Gilead’s ability to submit its regulatory application for BIC/FTC/TAF in the European

Union in the currently anticipated timeline. 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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