Gilead's Investigational Fixed-Dose Combination of Bictegravir, Emtricitabine and Tenofovir Alafenamide for the Treatment of HIV-1 Meets Primary Endpoint in Four Phase 3 Studies

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– U.S. NDA Submission Planned for Q2 2017; EU MAA Filing Planned for Q3 2017 –

FOSTER CITY, Calif.--(BUSINESS WIRE)--May 30, 2017-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that four Phase 3 studies evaluating a fixed-dose combination of bictegravir (50mg) (BIC), a novel investigational integrase strand transfer inhibitor (INSTI), and emtricitabine/tenofovir alafenamide (200/25mg) (FTC/TAF) for the treatment of HIV-1 infection met their primary objectives of non-inferiority. Three of the ongoing studies are designed to explore the efficacy and safety of BIC/FTC/TAF compared to regimens containing dolutegravir (50mg) (DTG) among treatment-naïve patients (Studies 1489 and 1490), and among virologically suppressed patients switching from an existing antiretroviral regimen (Study 1844). 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 (Study 1878).

"Since the approval of Viread 16 years ago, Gilead has continually worked to develop and improve treatments for people living with HIV. This investigational single tablet regimen brings together the potency of an integrase inhibitor, bictegravir, with the demonstrated efficacy and safety profile of the FTC/TAF backbone," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Based on the results from these Phase 3 studies, the combination of bictegravir and FTC/TAF could represent an important advance in triple-therapy treatment for a broad range of HIV patients, and we look forward to submitting regulatory applications in the U.S. and EU this year."

Studies 1489 and 1490 are double-blind studies in which treatment-naïve patients (n=600 in each study) were randomized 1:1 to receive BIC/FTC/TAF and abacavir/dolutegravir/lamivudine (600/50/300mg) (ABC/DTG/3TC) (Study 1489) or DTG+FTC/TAF (Study 1490). The primary endpoint is proportion of patients with HIV-1 RNA levels <50 copies/mL at Week 48, and the lower bound of the 95 percent CI for non-inferiority is 12 percent. The studies remain blinded through 144 weeks.

In study 1844, patients (n=520) who were virologically suppressed (HIV-1 RNA levels <50 copies/mL) on a regimen of ABC/DTG/3TC or DTG+ABC/3TC were randomized 1:1 to stay on their existing regimen or switch to BIC/FTC/TAF in a blinded manner. Study 1878 is an open-label study in which patients (n=520) who were virologically suppressed on a boosted protease inhibitor of darunavir (800mg) or atazanavir (300mg) plus a nucleoside/nucleotide backbone of ABC/3TC or emtricitabine/tenofovir disoproxil fumarate (200/300mg) were randomized 1:1 to either maintain their current regimen or switch to BIC/FTC/TAF. The primary endpoint in these studies is the proportion of patients with HIV RNA ≥50 copies/mL at Week 48, and the lower bound of the 95 percent CI for non-inferiority is 4 percent. Both studies were randomized through 48 weeks, after which point patients continuing in the studies enter an open-label extension receiving BIC/FTC/TAF.

BIC/FTC/TAF met the definition of non-inferiority in all four studies, with comparable proportions of patients having HIV-1 RNA <50 copies/mL (Studies 1489 and 1490) and HIV-1 RNA ≥50 copies/mL (Studies 1844 and 1878). In all studies BIC/FTC/TAF was well tolerated and no patients discontinued study medication due to renal events. No patients randomized to the bictegravir or dolutegravir arms developed treatment-emergent resistance. One patient randomized to the protease inhibitor arm in Study 1878 developed an abacavir resistance mutation (L74V).

Gilead plans to submit data from these Phase 3 studies for presentations at scientific conferences in 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.

Further information about the clinical studies can be found at www.clinicaltrials.gov.

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 risks related to its ability to submit regulatory applications for BIC/FTC/TAF in the United States and European Union in the currently anticipated timelines. In addition, there is the possibility that any regulatory applications submitted may not get approved or may have significant limitations on the product's 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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