Gilead's Investigational Fixed-Dose Combination of Emtricitabine/Tenofovir Alafenamide (F/TAF) Meets Primary 48-Week Objective in Phase 3 Study

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– F/TAF Currently Under Review for Marketing Approval by U.S. and European Regulatory Agencies –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Sep. 2, 2015-- Gilead Sciences, Inc. (NASDAQ:GILD) today announced that a Phase 3 study evaluating its investigational fixed-dose combination of emtricitabine and tenofovir alafenamide (200/10 mg and 200/25 mg) (F/TAF) for the treatment of HIV-1 infection met its primary objective. The ongoing study was designed to explore the efficacy and safety of F/TAF-based regimens among virologically suppressed adult patients switching from HIV treatment regimens containing emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) (Truvada®). At Week 48, the F/TAF-based regimens and the TDF-based regimens achieved similar rates of virologic suppression based on the proportion of patients with HIV RNA levels (viral load) of less than 50 copies/mL (94.3 percent for F/TAF-based regimens versus 93.0 percent for TDF-based regimens; difference in percentages: 1.3 percent, 95 percent CI: -2.5 percent to 5.1 percent).

Compared to the TDF-based regimens, the F/TAF-based regimens demonstrated statistically significant differences in mean bone mineral density (BMD) at the hip and spine ($p<0.001$) and in the median change in estimated glomerular filtration rate (eGFR) ($p<0.001$). General safety and discontinuation rates due to adverse events were comparable between the two arms. The most commonly reported adverse events included upper respiratory tract infection, diarrhea, nasopharyngitis, headache and bronchitis. Both regimens were generally well tolerated. Gilead plans to submit these data for presentation at a scientific conference in 2016.

"For more than a decade, Truvada has been a cornerstone of HIV therapy, and the results of this and other recent trials demonstrate the potential of F/TAF to become a next-generation backbone," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "The results from this study reinforce the efficacy, as well as the renal and bone safety advantages of TAF for patients who face a lifetime of treatment."

In April 2015, Gilead filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for two fixed-dose combinations of F/TAF (200/10 mg and 200/25 mg), and the FDA has set a target review date under the Prescription Drug User Fee Act of April 7, 2016. A Marketing Authorization Application (MAA) in the European Union for F/TAF was fully validated on May 28, 2015.

TAF and TAF-based regimens are investigational products and have not been determined to be safe or efficacious.

About the Study

The Phase 3 study is a randomized, double-blind clinical trial among 663 virologically suppressed adults (HIV-1 RNA levels < 50 copies/mL) on a stable regimen containing Truvada for ≥ six consecutive months. Patients were randomized 1:1 to either maintain their Truvada-based regimen (Truvada + placebo + third agent) or switch to an F/TAF-based regimen (F/TAF + placebo + third agent). The study will follow patients for 96 weeks after randomization. The daily dose of F/TAF in the trial was 200/25 mg; if used in combination with a protease inhibitor administered with either ritonavir or cobicistat, the daily dose was 200/10 mg.

The study is ongoing. The primary objective is to evaluate the efficacy of switching FTC/TDF to F/TAF versus maintaining FTC/TDF in HIV-1 positive subjects who are virologically suppressed on regimens containing FTC/TDF as determined by the proportion of subjects with HIV-1 RNA < 50 copies/mL at Week 48 as defined by the FDA snapshot analysis. The secondary objectives are to evaluate the renal safety of the two regimens including estimated glomerular filtration rate (eGFR), and to evaluate the bone safety of the two regimens in hip and spine bone mineral density (BMD)

at Week 48 and Week 96.

Additional information about the study can be found at www.clinicaltrials.gov.

About Tenofovir Alafenamide

TAF is an investigational novel nucleotide reverse transcriptase inhibitor (NRTI) that has demonstrated high antiviral efficacy at a dose less than one-tenth that of Gilead's Viread® (TDF), as well as improved renal and bone laboratory parameters compared to TDF in earlier clinical trials in combination with other antiretroviral agents.

In addition to F/TAF, Gilead has filed NDAs with the FDA for two other TAF-based HIV medicines: an investigational, once-daily single tablet regimen containing elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and TAF 10 mg (E/C/F/TAF); and an investigational, once-daily single tablet regimen that combines Gilead's emtricitabine (200 mg) and TAF (25 mg) with rilpivirine (25 mg) (R/F/TAF) from Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the treatment of adult and pediatric patients 12 years of age and older. Under the Prescription Drug User Fee Act, the FDA has set a target action date of November 5, 2015, for E/C/F/TAF and March 1, 2016, for R/F/TAF. MAAs in the European Union were fully validated on December 23, 2014, and August 20, 2015, for E/C/F/TAF and R/F/TAF, respectively.

A fourth investigational TAF-based regimen containing Gilead's TAF, emtricitabine and cobicistat, and Janssen's darunavir (D/C/F/TAF) is also under development under a separate licensing agreement. Under the agreement, Gilead is transferring to Janssen further development of the regimen and, subject to regulatory approval, the manufacturing, registration, distribution and commercialization of the product worldwide.

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.

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 the FDA and other regulatory authorities may not approve F/TAF, E/C/F/TAF, R/F/TAF, D/C/F/TAF and other F/TAF-based regimens in the currently anticipated timelines or at all, and marketing approvals, if granted, may have significant limitations on their use. As a result, F/TAF, E/C/F/TAF, R/F/TAF, D/C/F/TAF and other F/TAF-based regimens may never be successfully commercialized. In addition, Gilead may be unable to file for regulatory approval for these TAF-based regimens with the FDA and other regulatory authorities in the currently anticipated timelines. 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-Q for the quarter ended June 30, 2015, 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.

*U.S. full prescribing information for Viread and Truvada, including **BOXED WARNING**, is available at www.gilead.com.*

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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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