Gilead Presents Results From Phase 3 Study Evaluating Patients Who Switched to Investigational Fixed-Dose Combination of Bictegravir, Emtricitabine and Tenofovir Alafenamide From Boosted Protease Inhibitor-Based Regimens

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– Bictegravir-Containing Regimen Found to Be Non-Inferior to Boosted Protease Inhibitor-based Regimens in Virologically Suppressed Adult Patients with HIV–

– No Patients in Bictegravir Treatment Arm Demonstrated Treatment-Emergent Resistance Through 48 Weeks –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 4, 2017-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced detailed 48-week results from a Phase 3 study (Study 1878) evaluating the efficacy and safety of switching virologically suppressed HIV-1 infected adult patients from a multi-tablet regimen containing a boosted protease inhibitor (bPI) to a fixed-dose combination of bictegravir (50 mg) (BIC), a novel investigational integrase strand transfer inhibitor (INSTI), and emtricitabine/tenofovir alafenamide (200/25 mg) (FTC/TAF), a dual-NRTI backbone. In the ongoing study, BIC/FTC/TAF was found to be statistically non-inferior to regimens containing bPIs and demonstrated no treatment-emergent resistance at 48 weeks. The data are being presented at IDWeek 2017 in San Diego (Session 228).

“These data demonstrate the potential of BIC/FTC/TAF to match the efficacy of a boosted protease inhibitor regimen while also offering a high barrier to resistance and fewer interactions with other drugs,” said Eric Daar, MD, Chief of the Division of HIV Medicine at Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center and lead author of Study 1878. “The findings, along with data from three other Phase 3 studies in both treatment-experienced and treatment-naïve patients, suggest that the investigational regimen of BIC/FTC/TAF may be appropriate for a broad range of people living with HIV.”

In Study 1878, a total of 577 virologically suppressed adults with HIV taking regimens of boosted atazanavir (ATV) or darunavir (DRV) + abacavir/lamivudine (ABC/3TC) or FTC/tenofovir disoproxil fumarate (TDF) were randomized 1:1 to continue their bPI regimen or to switch to open-label coformulated BIC/FTC/TAF once daily. At the primary endpoint of Week 48, switching to BIC/FTC/TAF was non-inferior to continuing on a bPI regimen with 1.7 percent of patients in each group having HIV-1 RNA ≥50 c/mL (difference: 0.0 percent, 95 percent CI: -2.5 percent to 2.5 percent, p=1.00); the proportion of patients with HIV-1 RNA <50 c/mL was 92.1 percent in the BIC/FTC/TAF arm and 88.9 percent in the bPI arm, according to FDA snapshot algorithm.

No patients in the BIC/FTC/TAF arm developed treatment-emergent resistance, and one participant on DRV/ritonavir + ABC/3TC developed a treatment-emergent NRTI mutation associated with abacavir. No renal adverse events leading to discontinuations or cases of proximal renal tubulopathy occurred with BIC/FTC/TAF. The incidence of grade 3 or 4 adverse events was 4 percent (n=13) for the BIC/FTC/TAF arm versus 6 percent (n=18) for the bPI arm; the incidence of grade 3 or 4 laboratory abnormalities was 16 percent (n=45) for the BIC/FTC/TAF arm versus 29 percent (n=83) for the bPI arm. The most commonly reported adverse events (all grades) in both arms included headache, diarrhea, nasopharyngitis and upper respiratory tract infection.

“The combination of the unboosted integrase inhibitor bictegravir with the FTC/TAF backbone has the potential to further evolve HIV triple therapy with convenient dosing in a single-tablet regimen,” said Norbert W. Bischofberger, PhD, Gilead’s Executive Vice President, Research and Development and Chief Scientific Officer. “We look forward to the opportunity to offer patients this next-generation therapy as part of our TAF-based portfolio of treatments for HIV.”

Gilead filed a New Drug Application for BIC/FTC/TAF with a Priority Review voucher on June 12, 2017, and the U.S. Food and Drug Administration (FDA) set a target action date of February 12, 2018, under the Prescription Drug User Fee Act. A marketing application for BIC/FTC/TAF is also under review in the European Union and was validated by the European Medicines Agency (EMA) on July 13.

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.

Further information about the clinical trials 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 the possibility that regulatory authorities, including the FDA and EMA, 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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Gilead Sciences, Inc.
Investors
Sung Lee, 650-524-7792
or
Media
Ryan McKeel, 650-377-3548