Gilead's Investigational Tenofovir Alafenamide (TAF)-Based Single Tablet HIV Regimen Meets 48-Week Primary Objective in Two Phase 3 Studies

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-- U.S. and EU Filings Planned for Q4 2014 --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Sep. 24, 2014-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that two Phase 3 clinical trials (Studies 104 and 111) evaluating an investigational once-daily single tablet regimen containing tenofovir alafenamide (TAF) for the treatment of HIV-1 infection in treatment-naïve adults met their primary objectives. The studies demonstrated that the single tablet regimen comprising elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and TAF 10 mg (E/C/F/TAF), was non-inferior to Gilead's Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) based on the proportion of patients with HIV RNA levels (viral load) of less than 50 copies/mL at 48 weeks of therapy. In addition, E/C/F/TAF demonstrated more favorable renal and bone safety compared to Stribild.

"As individuals with HIV are living longer, there is a need for treatments that are not only highly effective, but also offer an improved safety profile," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Based on these Phase 3 results, we believe that the E/C/F/TAF single tablet regimen has the potential to optimize HIV therapy for a wide range of treatment-naïve patients."

In Study 104, 93.1 percent (n=405/435) of patients taking E/C/F/TAF compared to 92.4 percent (n=399/432), of patients taking Stribild, with 95 percent CI from -2.6% to 4.5%, achieved HIV RNA of less than 50 copies/mL at week 48. In Study 111, 91.6 percent (n=395/431) of E/C/F/TAF patients compared to 88.5 percent (n=385/435) of Stribild patients, with 95 percent CI from -1.0% to 7.1%, achieved HIV RNA of less than 50 copies/mL at week 48. Both regimens were generally well tolerated. Discontinuation rates due to adverse events, safety and resistance profiles were comparable between E/C/F/TAF and Stribild in both studies.

Laboratory abnormalities were generally similar for both regimens, with the exception of renal and bone safety indicators, which favored the TAF-based regimen. There was a statistically significant difference in the median change in estimated glomerular filtration rate (eGFR) from baseline to week 48, favoring the TAF-based regimen (-6.8 mL/min for E/C/F/TAF vs. -10.4 mL/min for Stribild in Study 104 ($p<0.001$); -5.7 mL/min for E/C/F/TAF vs. -11.9 mL/min for Stribild in Study 111 ($p<0.001$)). Additionally, patients taking the TAF-based regimen experienced a significantly smaller median percentage decrease from baseline in lumbar spine bone mineral density compared to Stribild patients (-1.19 vs. -2.67 in Study 104 ($p<0.001$); -1.11 vs. -2.81 in Study 111 ($p<0.001$)) and in hip bone mineral density (-0.77 vs. -3.24 in Study 104 ($p<0.001$); -0.74 vs. -2.78 in Study 111 ($p<0.001$)).

In Study 104, median changes from baseline in total fasting cholesterol, HDL (high-density lipoprotein or "good" cholesterol) and LDL (low-density lipoprotein or "bad" cholesterol) were, respectively, 30, 7 and 15 mg/dL for E/C/F/TAF and 12, 3 and 2 mg/dL for Stribild (total cholesterol, $p<0.001$; HDL, $p<0.001$; LDL, $p<0.001$). In Study 111, median changes from baseline in total cholesterol, HDL and LDL were respectively, 27, 7 and 11 mg/dL for E/C/F/TAF and 14, 4 and 2 mg/dL for Stribild (total cholesterol, $p<0.001$; HDL, $p<0.001$; LDL, $p<0.001$).

Gilead plans to submit data from Studies 104 and 111 for presentation to a scientific conference in early 2015.

Several additional ongoing Phase 3 studies are evaluating E/C/F/TAF among multiple HIV patient populations, including patients who switch to E/C/F/TAF from either a single tablet or multi-pill Truvada-containing regimens, patients with a history of antiviral drug resistance, patients with mild to moderate renal impairment and treatment-naïve HIV-positive adolescents. An additional Phase 3b study, WAVES, is evaluating E/C/F/TAF among HIV-positive women who switched from a multi-pill regimen.

Based on the results of Studies 104 and 111 and data from these additional ongoing studies, Gilead plans to submit regulatory applications for E/C/F/TAF in the United States and European Union in the fourth quarter of 2014.

About the E/C/F/TAF Studies

Study 104 and Study 111 are randomized, double-blind, 96-week clinical trials among 1,744 treatment-naïve HIV-1 infected adults with viral load greater than or equal to 1,000 copies/mL. In Study 104, 867 patients were randomized (1:1) and received E/C/F/TAF (n=435) or Stribild (n=432). In Study 111, 866 patients were randomized (1:1) and received E/C/F/TAF (n=431) or Stribild (n=435).

The primary efficacy endpoint of the studies is the proportion of patients with viral load < 50 copies/mL at 48 weeks of treatment as determined by the FDA-defined snapshot analysis. Key secondary endpoints include change from baseline in bone mineral density at the hip and spine at weeks 48, and change from baseline in serum creatinine at weeks 48. Other secondary endpoints include the proportion of patients with viral load < 20 copies/mL at 48 and 96 weeks of therapy as defined by the FDA snapshot analysis, the proportion of patients with viral load < 50 copies/mL at week 96 as defined by the FDA snapshot and change from baseline in CD4+ cell count at weeks 48 and 96.

The studies are ongoing in a blinded fashion. After week 96, patients will continue to take their blinded study drug until treatment assignments have been unblinded, at which point all will be given the option to participate in an open-label rollover extension and receive E/C/F/TAF. Additional information about the study can be found at www.clinicaltrials.gov.

Elvitegravir, cobicistat and E/C/F/TAF are investigational products in the United States and have not yet been determined safe or efficacious in humans.

About Tenofovir Alafenamide

Tenofovir alafenamide (TAF) is a nucleotide reverse transcriptase inhibitor (NtRTI). It is an investigational novel prodrug of tenofovir, the active agent in Viread® (tenofovir disoproxil fumarate), which is also an NtRTI. Phase 1b dose-ranging studies identified a dose of TAF that is ten times lower than Viread. The smaller milligram size of TAF may enable the development of new fixed-dose combinations and single tablet regimens for HIV therapy that are not feasible with Viread.

About Elvitegravir

Elvitegravir is a member of the integrase inhibitor class of antiretroviral compounds, which interfere with HIV replication by blocking the ability of the virus to integrate into the genetic material of human cells. Elvitegravir was licensed by Gilead from Japan Tobacco Inc. (JT) in March 2005. Under the terms of Gilead's agreement with JT, Gilead has exclusive rights to develop and commercialize elvitegravir in all countries of the world, excluding Japan, where JT retains rights. Elvitegravir is approved under the tradename Vitekta® in Europe, Australia and Canada, and is currently under review by the U.S. Food and Drug Administration.

About Cobicistat

Cobicistat is a cytochrome P450 3A (CYP3A) inhibitor. It boosts blood levels of the HIV protease inhibitors atazanavir and darunavir by suppressing CYP3A, an enzyme that metabolizes these drugs in the body. Cobicistat acts only as a pharmacokinetic enhancer and has no antiviral activity. Cobicistat is approved under the tradename Tybost® in Europe, Australia and Canada, and is currently under review by the U.S. Food and Drug Administration.

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 worldwide. Headquartered in Foster City, California, Gilead has operations in North and South America, Europe

and Asia Pacific.

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 E/C/F/TAF in the United States and European Union in the currently anticipated timelines. In addition, we may observe unfavorable results from longer-term clinical trials involving E/C/F/TAF or other TAF-based regimens. In addition, Gilead may make a strategic decision to discontinue development of E/C/F/TAF or other TAF-based regimens if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. Further, Gilead may be unable to obtain approvals from regulatory authorities for E/C/F/TAF, elvitegravir or cobicistat, and marketing approvals, if granted, may have significant limitations on their use. As a result, these product candidates 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, 2014, 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 including BOXED WARNING for Stribild and Viread is available at www.gilead.com.

Stribild, Tybost, Viread and Vitekta are registered trademarks of Gilead Sciences, Inc.

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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