Gilead Submits New Drug Application to U.S. Food and Drug Administration for Tenofovir Alafenamide (TAF)-Based Single Tablet Regimen for HIV

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– High Rates of Viral Suppression and Improved Renal and Bone Safety Demonstrated in Phase 3 Studies –

– First of Several TAF-Based Single Tablet Regimens Being Evaluated by Gilead –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 6, 2014-- 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 elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide (TAF) 10 mg (E/C/F/TAF) for the treatment of HIV-1 infection in adults. The data submitted in the NDA support the use of the regimen among adult and adolescent treatment-naïve HIV individuals, virologically suppressed patients who switch regimens and those with renal impairment. If approved, E/C/F/TAF would be Gilead's first single tablet regimen to contain TAF.

TAF is an investigational, novel prodrug of tenofovir, the active agent in Gilead's Viread® (tenofovir disoproxil fumarate). TAF is a more targeted form of tenofovir than Viread that has demonstrated high antiviral efficacy at a dose that is 10 times lower, as well as an improved renal and bone safety profile.

"This TAF-based regimen has the potential to provide a range of HIV patients with a highly effective and well-tolerated new treatment option with a favorable safety profile," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Gilead remains focused on advancing next-generation therapies that have the potential to improve HIV treatment over the long-term and TAF will be the cornerstone of future Gilead single tablet regimens."

The NDA for E/C/F/TAF is supported by 48-week data from two pivotal Phase 3 studies (Studies 104 and 111) in which the regimen met its primary objective of non-inferiority compared to Gilead's Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) among treatment-naïve patients. In the studies, E/C/F/TAF demonstrated improved renal and bone safety compared to Stribild. The NDA is also supported by data from additional Phase 3 studies evaluating the TAF-based regimen among virologically suppressed patients who switched to E/C/F/TAF and among patients with renal impairment. In addition, the filing is supported by Chemistry, Manufacturing and Controls (CMC) information on the individual components and the co-formulated single tablet regimen.

Gilead plans to submit a regulatory application for E/C/F/TAF in the European Union by the end of 2014.

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

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 the risk that the FDA and other regulatory agencies may not approve E/C/F/TAF, and that any marketing approvals, if granted, may have significant limitations on its use. Further, even if approved, Gilead may not be able to successfully commercialize E/C/F/TAF and may make a strategic

decision to discontinue its development if, for example, the market for the product fails to materialize as expected. In addition, Gilead may be unable to file for regulatory approval for E/C/F/TAF 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 Quarterly Report on Form 10-Q for the quarter ended September 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 for Stribild and Viread, including **BOXED WARNING** for both products, 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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