European CHMP Adopts Positive Opinion for Gilead's Single Tablet Regimen Genvoya® (Elvitegravir, Cobicistat, Emtricitabine and Tenofovir Alafenamide) for the Treatment of HIV

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– Gilead's First TAF-based Regimen to Receive CHMP Positive Opinion –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Sep. 25, 2015-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has adopted a positive opinion on the company's Marketing Authorization Application (MAA) for the investigational, once-daily single tablet regimen Genvoya® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide (TAF) 10 mg) for the treatment of HIV-1 infection. The data submitted in the MAA support the use of the regimen among adult and adolescent treatment-naïve individuals, virologically suppressed adults who switch regimens and adults with mild-to-moderate renal impairment.

The CHMP's recommendation will now be reviewed by the European Commission, which has the authority to approve medicines for use in the 28 countries of the European Union. If authorized, Genvoya would be Gilead's first single tablet regimen to contain TAF.

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

The MAA for Genvoya 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 adult patients. In the studies, Genvoya demonstrated improvement in surrogate laboratory markers of renal and bone safety as compared to Stribild. The MAA is also supported by data from additional Phase 3 studies evaluating the TAF-based regimen among adolescents, virologically suppressed adult patients who switched to Genvoya and adult patients with mild-to-moderate renal impairment.

In addition to Genvoya, two other TAF-based regimens are currently under evaluation by the EMA. The first is an investigational, fixed-dose combination of emtricitabine 200 mg and tenofovir alafenamide 25 or 10 mg (F/TAF) for use in combination with other antiretroviral agents. The second is an investigational, once-daily single tablet regimen that combines emtricitabine 200 mg, tenofovir alafenamide 25 mg and rilpivirine 25 mg (R/F/TAF). Emtricitabine and tenofovir alafenamide are from Gilead Sciences and rilpivirine is from Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

TAF and all TAF-based regimens are investigational products and their safety and efficacy have not been established in the European Union.

About Gilead

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 risk that the MAA for Genvoya, F/TAF

and/or R/F/TAF may not be approved by the EMA, and marketing approvals, if granted, may have significant limitations on their 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 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.

The European SmPCs for Stribild and Viread are available from the EMA website at www.ema.europa.eu.

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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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Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Investors:
Sung Lee, +1 650-524-7792
Media (U.S.):
Ryan McKeel, +1 650-377-3548
Media (EU):
Kristine Kelly, +44 (0)78 1086 8956