European Commission Grants Marketing Authorization for Gilead's Single Tablet Regimen Genvoya® (Elvitegravir, Cobicistat, Emtricitabine and Tenofovir Alafenamide) for the Treatment of HIV-1 Infection

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– Gilead's First TAF-based Single Tablet Regimen Demonstrates High Efficacy with Improved Renal and Bone Parameters Compared to TDF-based Regimens –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 23, 2015-- Gilead Sciences, Inc. (NASDAQ:GILD) today announced that the European Commission has granted marketing authorization for the once-daily single tablet regimen Genvoya® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg or E/C/F/TAF) for the treatment of HIV-1 infection. Genvoya is the first TAF-based regimen to receive marketing authorization in the European Union (EU).

Genvoya is indicated in the EU for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with HIV-1 without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir.

"With access to appropriate treatment, HIV patients today have the potential to live nearly as long as the general population. However, research shows they are at an increased risk of age- and treatment-related comorbidities, which means helping preserve long-term health should be a priority when making treatment decisions," said Anton Pozniak, HIV Service Director, Chelsea and Westminster Hospital, London, UK. "With Genvoya, we have an important new treatment option for a range of HIV patients, as it offers both demonstrated sustained viral suppression and improvements in renal and bone safety markers compared to TDF-based regimens."

Photos and multimedia gallery available at www.GileadHIVEU.com.

Today's marketing authorization is based on a Phase 3 HIV clinical program in more than 3,500 patients across 21 countries, including treatment-naïve, virologically suppressed, renally impaired and adolescent patients. It allows for the marketing of Genvoya in all 28 countries of the EU.

TAF is a novel targeted prodrug of tenofovir that has demonstrated high antiviral efficacy similar to and 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. Data show that because TAF enters cells, including HIV-infected cells, more efficiently than TDF, it can be given at a lower dose resulting in 91 percent less tenofovir in the bloodstream.

"For more than 25 years, Gilead has continually worked to develop new treatments to improve the management of HIV," said Norbert W. Bischofberger, PhD, Gilead's Executive Vice President, Research and Development and Chief Scientific Officer. "Genvoya, along with other investigational products in our TAF-based portfolio, have the potential to deliver long-term health benefits to people living with HIV across Europe and around the world."

The marketing authorization is supported by 48-week data from two ongoing Phase 3 studies (Studies 104 and 111) among 1,733 treatment-naïve adult patients in which the regimen met its primary endpoint of non-inferiority compared to Stribild® (elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg or E/C/F/TDF). In the combined analysis of the studies, 92.4 percent of Genvoya patients and 90.4 percent of Stribild patients had HIV-1 RNA levels less than 50 copies/mL at Week 48. Certain renal and bone laboratory parameters favored Genvoya over Stribild.

Additionally, the approval is supported by a Phase 3 study (Study 109) among virologically suppressed adult patients who were randomized either to stay on their TDF-based regimen or switch to Genvoya. The study enrolled 1,436

subjects. At Week 48, switching to Genvoya was found to be statistically superior to remaining on TDF-based regimens based on the percentages of patients with HIV-1 RNA levels less than 50 copies/mL. Patients receiving Genvoya also demonstrated improvements in certain bone and renal laboratory parameters compared to those who stayed on their TDF-based baseline regimen. Finally, data from two studies evaluating Genvoya among treatment-naïve adolescents and among virologically suppressed adult patients with mild-to-moderate renal impairment (eGFR between 30-69ml/min) supported the approval.

For important safety information for Genvoya, including contraindications, special warnings, drug interactions, and adverse drug reactions, please see the European SmPC for Genvoya, available from the EMA website at www.ema.europa.eu.

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 and rilpivirine is from Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

F/TAF and R/F/TAF are investigational products and their efficacy and safety have yet 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 Genvoya may not be approved by other regulatory authorities and the marketing applications for 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 September 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 Genvoya, Stribild and Viread are available from the EMA website at www.ema.europa.eu.

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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