European CHMP Adopts Positive Opinion for Gilead's Fixed-Dose Combination Descovy® (Emtricitabine/Tenofovir Alafenamide) for the Treatment of HIV

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 26, 2016-- 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 two doses of Descovy® (emtricitabine and tenofovir alafenamide 200/10 mg and 200/25 mg; F/TAF), an investigational fixed-dose combination for the treatment of HIV-1 infection in adults and adolescents (ages 12 years and older with body weight at least 35 kg) in combination with other HIV antiretroviral agents.

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). TAF has also demonstrated 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 much lower dose and there is 90 percent less tenofovir in the bloodstream.

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.

The MAA for Descovy is supported by 48-week data from two pivotal Phase 3 studies (Studies 104 and 111) in which the F/TAF-based regimen (administered as Genvoya®; elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg, E/C/F/TAF) met its primary objective of non-inferiority compared to an F/TDF-based regimen (administered as Stribild®; elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg, E/C/F/TDF) among treatment naïve adult patients. In the studies, the F/TAF-based regimen demonstrated statistically significant improvements in surrogate laboratory markers of renal and bone safety as compared to the F/TDF-based regimen. The MAA is also supported by data from an additional Phase 3 study evaluating Descovy among virologically suppressed adults who switched regimens (Study 1089), and studies evaluating the F/TAF-based regimen (administered as Genvoya) among adults with mild-to-moderate renal impairment and among adolescents. Lastly, bioequivalence studies demonstrated that the formulation of the fixed-dose combinations of Descovy achieved the same drug levels of TAF and emtricitabine in the blood as in Genvoya.

Descovy is an investigational product and its 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 Descovy may not be approved by the European Commission or other regulatory authorities, and marketing approvals, if granted, may have significant limitations on its use. As a result, Gilead may not be able to successfully commercialize Descovy. 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 Annual Report on Form 10-K for the year ended December 31, 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.

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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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