European CHMP Adopts Positive Opinion for Gilead's TAF-Based Single Tablet Regimen Odefsey® (Emtricitabine, Rilpivirine, Tenofovir Alafenamide) for Treatment of HIV

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 29, 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 Odefsey® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg; R/F/TAF), an investigational single tablet regimen for the treatment of HIV-1 infection in adults and adolescents (ages 12 years and older with body weight at least 35 kg) without known mutations associated with resistance to the NNRTI class, tenofovir or emtricitabine, and with a viral load less than 100,000 copies per mL. Odefsey combines Gilead's emtricitabine and tenofovir alafenamide with rilpivirine, owned by Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, and marketed by Janssen Cilag International NV.

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 Odefsey is supported by a bioequivalence study demonstrating that Odefsey achieved similar drug levels of emtricitabine and TAF in the blood as Genvoya® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg; E/C/F/TAF) and similar drug levels of rilpivirine as Edurant® (rilpivirine 25 mg). The safety, efficacy and tolerability of Odefsey are supported by clinical studies of rilpivirine-based therapy (administered as R+F/TDF or Eviplera®; R/F/TDF) and F/TAF-based therapy (administered as Genvoya) in a range of patients with HIV-1 infection. These patients include treatment-naïve adults and adolescents, virologically suppressed adults who switched from protease inhibitor-based regimens, non-nucleoside reverse-transcriptase inhibitor-based regimens, or integrase strand transfer inhibitor-based regimens, and virologically suppressed adults with mild-to-moderate renal impairment.

The Odefsey CHMP opinion is part of an ongoing development and commercialization agreement between Gilead and Janssen, first established in 2009. Under this agreement, and pending the product's approval, Gilead will be responsible for the manufacturing, registration, distribution and commercialization of the product in most countries, while Janssen will distribute it in approximately 17 markets and have co-detailing rights in several key markets, including the United States. The original agreement was established for the development and commercialization of Eviplera, marketed as Complera® in the United States, and was expanded in 2014 to include Odefsey.

In the European Union, Odefsey is an investigational product and its efficacy and safety have yet not been established.

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 Odefsey 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 Odefsey. 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 Eviplera®, Edurant®, Genvoya® and Viread® and are available from the EMA website at www.ema.europa.eu.

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Edurant® is a registered trademark of Janssen Sciences Ireland UC.

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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