European Commission Grants Marketing Authorization for Gilead's Single Tablet Regimen Odefsey® (Emtricitabine, Rilpivirine, Tenofovir Alafenamide) for the Treatment of HIV

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– Odefsey is the Second Single Tablet Regimen Containing the Descovy Backbone and the Third Product in Gilead's New TAF Portfolio to be Approved in Europe –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jun. 23, 2016-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the European Commission has granted marketing authorization for the once-daily single tablet regimen (STR) Odefsey® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg or R/F/TAF) for the treatment of HIV-1 infection in certain patients. Odefsey combines Gilead's emtricitabine and tenofovir alafenamide (marketed as Descovy®) with rilpivirine, marketed by Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Following the approval of Genvoya in November 2015, Odefsey is Gilead's second STR based on the Descovy backbone to receive marketing authorization in the European Union and is currently the smallest pill of any STR for the treatment of HIV.

Odefsey is indicated in the European Union for the treatment of adults and adolescents (ages 12 years and older with body weight at least 35 kg) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with a viral load less than 100,000 HIV-1 RNA copies/ml.

"People living with HIV today are increasingly likely to be receiving treatment for other conditions – such as heart and liver disease – because they are living longer than ever before, exposing them for longer periods of time to the virus and to the medications used to treat it. Therefore, we need new treatment options that are not only efficacious but also tolerable, and with convenient dosing," said Andy Ustianowski, MD, North Manchester General Hospital. "Odefsey combines the antiviral efficacy and safety profile of the new Descovy backbone with the established tolerability profile of rilpivirine as a third agent."

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

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 approval of Odefsey underscores Gilead's ongoing commitment to researching and developing new treatment options to help address the evolving needs of a range of HIV patients," said Norbert W. Bischofberger, PhD, Gilead's Executive Vice President, Research and Development and Chief Scientific Officer. "Through our new portfolio of products based on the Descovy backbone, Gilead is pleased to offer effective treatments and simple dosing options for people living with HIV, which has now become a chronic condition for most patients."

The marketing authorization 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 also supported by clinical studies of rilpivirine-based therapy (administered as R+F/TDF or Eviplera®; emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 245 mg) 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, NNRTI-based regimens, or integrase strand transfer inhibitor-based regimens, and

virologically suppressed adults with mild-to-moderate renal impairment. As with all rilpivirine-containing regimens, Odefsey should be taken with food.

The Odefsey approval is part of an ongoing development and commercialization agreement between Gilead and Janssen, first established in 2009. Under this agreement, Gilead is responsible for the manufacturing, registration, distribution and commercialization of Odefsey in most countries, while Janssen will distribute it in approximately 18 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.

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

About Gilead

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercialises 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 physicians may not see the benefits of prescribing 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, 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 Descovy, Edurant, Eviplera, Genvoya, Odefsey and Viread and 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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