European Commission Grants Marketing Authorization for Gilead's Fixed-Dose Combination Descovy® (Emtricitabine, Tenofovir Alafenamide) for Treatment of HIV

April 25, 2016 7:11 AM ET

– Descovy is the First New HIV Treatment Backbone Approved in the EU in Over a Decade –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 25, 2016-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Commission has granted marketing authorization for two doses of Descovy® (emtricitabine and tenofovir alafenamide 200/10 mg and 200/25 mg; F/TAF), a fixed-dose combination for the treatment of HIV-1 infection. Descovy is Gilead's second TAF-based therapy to receive marketing authorization in the European Union.

Descovy 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) in combination with other HIV antiretroviral agents. The marketing authorization is based on a Phase 3 HIV clinical program evaluating F/TAF in combination with other antiretroviral agents in treatment naïve, virologically suppressed, renally impaired and adolescent patients. The marketing authorization allows for the marketing of Descovy in all 28 countries of the European Union.

"Treatment backbones, paired with a third agent, are a cornerstone for successful management of HIV. Descovy is the first new HIV backbone approved in Europe in more than a decade and represents an important advance in addressing the needs of patients," said Dr. José Arribas, Associate Professor of Medicine, Autonoma University School of Medicine, Madrid. "The components of Descovy, either as part of a single or multi tablet regimen, offer physicians and their patients a simple and effective combination with improvements in renal and bone lab safety parameters."

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.

"TAF represents the latest development in Gilead's more than 25-year history of innovation in the field of HIV, and we are pleased to offer patients and physicians another TAF-based therapy that expands their treatment options," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "We look forward to making Descovy available as quickly as possible throughout the European Union as we continue to advance a pipeline of HIV regimens that contain TAF."

The marketing authorization for Descovy is supported by 48-week data from a Phase 3 study (Study 1089) evaluating the safety and efficacy of switching virologically suppressed HIV-1 infected adult patients from regimens containing emtricitabine and tenofovir disoproxil fumarate (F/TDF; Truvada®) plus a third agent to regimens containing F/TAF plus the same third agent. At Week 48, the F/TAF-based regimens were found to be statistically non-inferior to the F/TDF-based regimens, based on percentages of patients with HIV-1 RNA levels less than 50 copies per mL. The study also demonstrated statistically significant improvements in renal and bone laboratory parameters among patients receiving the F/TAF-based regimens.

The marketing authorization is also supported by 48-week data from two pivotal Phase 3 studies (Studies 104 and 111) evaluating an F/TAF-based regimen (administered as Genvoya®; elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg; E/C/F/TAF) against 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 these studies, certain renal and bone laboratory parameters favored the F/TAF-based regimen over the F/TDF-based regimen. Additionally, the marketing authorization is supported by data from studies evaluating an

F/TAF-based regimen (administered as Genvoya) among adults with mild-to-moderate renal impairment and among treatment naïve 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.

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

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 physicians may not see benefits of prescribing 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 Descovy®, 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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Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Investors
Patrick O'Brien, +1 650-522-1936
or
Media (U.S.)
Ryan McKeel, +1 650-377-3548
or
Media (EU)
Stephen Head, +44 (0)7768 705945