Gilead Sciences Statement on U.S. Food and Drug Administration Advisory Committee's Recommendation on Descovy for PrEP™

August 8, 2019

FOSTER CITY, Calif.--(BUSINESS WIRE)--Aug. 7, 2019-- Gilead Sciences, Inc. (NASDAQ: GILD)announced today that theAntimicrobial Drugs Advisory Committee (AMDAC) of the U.S. Food and Drug Administration (FDA) recommended approval of Descovy® (emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets; F/TAF) for the proposed indication of pre-exposure prophylaxis (PrEP) in men and transgender women (TGW) who have sex with men by a vote of 16 to 2.

"We appreciate the advisory committee's thoughtful review and discussion of the data during today's meeting and look forward to collaborating with FDA to make this potential new prevention option available to people at risk of HIV in the United States," said Diana Brainard, MD, Senior Vice President, HIV and Emerging Viruses, Gilead Sciences. "Descovy represents a potential new therapeutic option for people at risk of sexually acquired HIV-1 infection. If approved for a PrEP indication, Descovy could play a meaningful role in the federal initiative to address the nation's HIV epidemic."

Prevention methods and practices are essential tools in the fight against HIV. PrEP is a vital tool in the fight against HIV and should be an available HIV prevention strategy for all appropriate individuals at risk for HIV infection. In addition, PrEP is included in clinical guidelines as part of a comprehensive prevention strategy for individuals at risk for HIV.

The AMDAC reviewed Descovy data from the DISCOVER global Phase 3 clinical study, which evaluated the safety and efficacy of Descovy compared with Truvada® in men and transgender women who have sex with men and are at high-risk for sexually acquired HIV infection. Results from the DISCOVER trial demonstrated that Descovy achieved non-inferiority to Truvada in study participants who were at substantial and sustained risk of HIV acquisition. Additionally, statistically significant improvements in renal and bone laboratory parameters were observed for participants receiving Descovy versus those receiving Truvada.

The AMDAC also evaluated pharmacokinetic data on Truvada and Descovy for HIV treatment and PrEP in support of the potential use of Descovy for PrEP in cis-gender women, a population that was not part of the DISCOVER study. The committee voted 10 to 8 that there were not adequate data regarding the efficacy of Descovy for PrEP in cis-women.

Gilead recognizes the value that Descovy could bring to HIV prevention efforts for the broadest possible at-risk population in the United States and will continue to work with FDA as the agency completes its review of the application.

The AMDAC is convened upon the request of FDA to review and evaluate safety and efficacy data of human products, including those for use in the treatment or prevention of HIV. While FDA is not bound by the committee's recommendation, the recommendations made by advisory committees, including the panel deliberations and voting, may be considered by the agency in making its final decision on an application.

Descovy was approved in April 2016 for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg, in combination with other antiretroviral agents.

Descovy for the prevention of HIV is an investigational use that has not been determined to be safe or efficacious and is not approved anywhere globally.

IMPORTANT U.S. SAFETY INFORMATION AND INDICATION FOR THE USE OF DESCOVY FOR HIV TREATMENT
BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Descovy is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of Descovy have not been established in patients coinfected with HIV-1 and HBV. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of Descovy. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue Descovy. If appropriate, initiation of anti-hepatitis B therapy may be warranted.**

Warnings and precautions

- Immune reconstitution syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported.
- New onset or worsening renal impairment: Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of FTC and tenofovir alafenamide with elvitegravir and cobicistat, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Do not initiate Descovy in patients with estimated creatinine clearance (CrCl) <30 mL/min. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue Descovy in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  Renal monitoring: In all patients, monitor CrCl, urine glucose, and urine protein prior to initiating and during therapy. In patients with chronic kidney disease, additionally monitor serum phosphorus.
- Lactic acidosis and severe hepatomegaly with steatosis: Fatal cases have been reported with the use of nucleoside

analogs, including FTC and TDF. Discontinue Descovy if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse reactions

- Most common adverse reaction (incidence ≥10%; all grades) in clinical studies was nausea (10%).

Drug interactions

- Prescribing information: Consult the full prescribing information for Descovy for more information on potentially significant drug interactions, including clinical comments.
- Metabolism: Drugs that inhibit P-gp can increase the concentrations of components of Descovy. Drugs that induce P-gp can decrease the concentrations of components of Descovy, which may lead to loss of efficacy and development of resistance.
- Drugs affecting renal function: Coadministration of Descovy with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of emtricitabine and tenofovir and the risk of adverse reactions.

Dosage and administration

- Dosage: Patients who weigh ≥25 kg: 1 tablet taken orally once daily with or without food.
- Renal impairment: Not recommended in patients with CrCl <30 mL/min.
- Testing prior to initiation: Test patients for HBV infection and assess CrCl, urine glucose and urine protein.
- Pediatrics: The safety and effectiveness of Descovy coadminstered with an HIV-1 protease inhibitor that is administered with either ritonavir or cobicistat have not been established in pediatric subjects weighing less than 35 kg.

Pregnancy and lactation

- Pregnancy: There is insufficient human data on the use of Descovy during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established; available data from the APR for FTC shows no difference in the rates of birth defects compared with a U.S. reference population.
- Lactation: Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

INDICATION

Descovy is indicated in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in patients weighing at least 35 kg.

Descovy is also indicated, in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor, for the treatment of HIV-1 infection in pediatric patients weighing at least 25 kg and less than 35 kg.

Limitations of Use:

Descovy is not indicated for use as pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV-1 infection.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

For nearly 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention, testing and linkage to care, and cure research. Today, it's estimated that more than 12 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company's manufacturing partners.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

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 FDA and other regulatory agencies may not approve Descovy for PrEP in the currently anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use. As a result, Descovy for PrEP may never be successfully commercialized. There is also the possibility of unfavorable results from additional studies involving Descovy for PrEP. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. 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 June 30, 2019, 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.

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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