

## **U.S. Food and Drug Administration Approves Descovy® (Emtricitabine, Tenofovir Alafenamide), Gilead's Third TAF-Based HIV Therapy**

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### ***– Fixed-Dose Combination HIV Treatment Backbone Can Be Paired with Range of Third Agents –***

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 4, 2016-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved Descovy® (emtricitabine 200 mg/tenofovir alafenamide 25 mg, F/TAF), a fixed-dose combination for the treatment of HIV. Descovy is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. Descovy is not indicated for use as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.

Descovy has a boxed warning in its product label regarding the risks of lactic acidosis/severe hepatomegaly with steatosis, and post treatment acute exacerbation of hepatitis B. See below for important safety information.

Photos and multimedia gallery available at [www.GileadHIVMedia.com](http://www.GileadHIVMedia.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.

“As the first new HIV treatment backbone approved by the FDA in more than a decade, Descovy represents an important evolution in HIV care. As part of a single tablet regimen or partnered with a third agent, the components of Descovy offer patients a simple and effective combination with a safety profile that has the potential to improve health,” said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. “With today’s approval, Gilead is now able to offer patients and providers in the United States a range of options from our TAF based-portfolio, which is designed to help address the diverse needs of HIV patients worldwide.”

The approval of 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 a 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. Tests of certain renal and bone laboratory parameters favored the F/TAF-based regimen over the F/TDF-based regimen.

The approval also is supported by a Phase 3 study (Study 109) evaluating the F/TAF-based regimen (administered as Genvoya) among virologically suppressed adult patients who switched from F/TDF-based regimens. In the study, the F/TAF-based regimen was found to be statistically non-inferior to the F/TDF-based regimens and demonstrated improvements in certain bone and renal laboratory parameters compared to the F/TDF-based regimens. Additionally, the approval is supported by data from Phase 3 studies evaluating the F/TAF-based regimen (administered as Genvoya) among virologically suppressed adults with mild-to-moderate renal impairment and among treatment naïve adolescents. Finally, bioequivalence studies demonstrated that Descovy achieved the same drug levels of TAF and emtricitabine in the blood as Genvoya.

Descovy does not cure HIV infection or AIDS.

### **Patient Assistance Programs**

Gilead's U.S. Advancing Access<sup>®</sup> program provides assistance to appropriate patients in the United States who are uninsured, underinsured or who need financial assistance to pay for their medications, including Descovy.

The program offers information and assistance for patients, including:

- Access to agents who can provide information related to coverage and insurance-related questions.
- The Advancing Access Copay Coupon Program, which provides co-pay assistance for eligible patients with private insurance who need assistance paying for out-of-pocket medication costs.
- The Advancing Access Patient Assistance Program and Truvada<sup>®</sup> Medication Assistance Program, which will provide Gilead medications at no charge for eligible patients with no other insurance options.

Additionally, Gilead is working closely with the ADAP Crisis Task Force, as the company has done for each of its other HIV medications, to provide discounts to state AIDS Drug Assistance Programs (ADAPs) that will help ensure access to Descovy for patients who receive medications through these programs.

Information about how to apply for any of these forms of assistance can be found at [www.GileadAdvancingAccess.com](http://www.GileadAdvancingAccess.com) or by calling 1-800-226-2056 between 9:00 a.m. and 8:00 p.m. EST.

### Important U.S. Safety Information for Descovy

#### **BOXED WARNING: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B**

- **Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs in combination with other antiretrovirals.**
- **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 coinfecting with HIV-1 and HBV. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfecting with HIV-1 and HBV and have discontinued products containing emtricitabine 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 coinfecting with HIV-1 and HBV and discontinue Descovy. If appropriate, initiation of anti-hepatitis B therapy may be warranted.**

#### Warnings and precautions

- **Fat redistribution** or accumulation has been observed in patients receiving antiretroviral therapy.
- **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 emtricitabine 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.
- **Bone loss and mineralization defects:** Decreases in bone mineral density (BMD) have been reported with the use of tenofovir prodrugs. Consider monitoring BMD in patients with a history of pathologic fracture or risk factors for bone loss. Mineralization defects, including osteomalacia associated with PRT, have been reported with the use of TDF-containing products.

## Adverse reactions

- **Most common adverse reaction** (incidence  $\geq 10\%$ ; 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 12 years and older ( $\geq 35$  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.

## Pregnancy and lactation

- **Pregnancy:** There are insufficient data on the use of Descovy during pregnancy. In animal studies, no adverse developmental effects were observed with the components of Descovy. An Antiretroviral Pregnancy Registry has been established.
- **Lactation:** Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

## 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 the 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.

*U.S. Full Prescribing Information, including **BOXED WARNING**, for Descovy, Genvoya, Stribild, Truvada and Viread are available at [www.gilead.com](http://www.gilead.com).*

*Descovy, Genvoya, Stribild, Truvada, Viread and Advancing Access are registered trademarks of Gilead Sciences, Inc., or its related companies.*

*For more information on Gilead Sciences, please visit the company's website at [www.gilead.com](http://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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