U.S. Food and Drug Administration Approves Gilead’s Vemlidy® (Tenofovir Alafenamide) for the Treatment of Chronic Hepatitis B Virus Infection

November 10, 2016 1:07 PM ET

-- Vemlidy is a Once-Daily Treatment that Demonstrated Similar Efficacy with Improved Renal and Bone Laboratory Safety Parameters Compared to Viread --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 10, 2016-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved Vemlidy® (tenofovir alafenamide, TAF) 25mg, a once-daily treatment for adults with chronic hepatitis B virus (HBV) infection with compensated liver disease.

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

Vemlidy is a novel, targeted prodrug of tenofovir that has demonstrated antiviral efficacy similar to and at a dose less than one-tenth that of Gilead’s Viread® (tenofovir disoproxil fumarate, TDF) 300mg. Data show that because Vemlidy has greater plasma stability and more efficiently delivers tenofovir to hepatocytes compared to Viread, it can be given at a lower dose, resulting in less tenofovir in the bloodstream. As a result, Vemlidy improved renal and bone laboratory safety parameters compared to Viread.

“Chronic hepatitis B is a life-threatening illness that affects up to 2.2 million people in the U.S.,” said Calvin Pan, MD, Clinical Professor of Medicine, NYU Langone Medical Center, and investigator in the Vemlidy clinical trials. “Clinical trials demonstrated Vemlidy is efficacious with improved renal and bone safety parameters compared to Viread, representing an important development for people living with this chronic disease.”


Vemlidy’s approval is supported by 48-week data from two international Phase 3 studies (Studies 108 and 110) among 1,298 treatment-naïve and treatment-experienced adult patients with chronic HBV infection. Study 108 randomized and treated 425 HBeAg-negative patients with either Vemlidy or Viread, and Study 110 randomized and treated 873 HBeAg-positive patients with either Vemlidy or Viread. Both studies met their primary endpoint of non-inferiority to Viread based on the percentage of patients with chronic hepatitis B with plasma HBV DNA levels below 29 IU/mL at 48 weeks of therapy.

In an integrated analysis of both studies, patients receiving Vemlidy demonstrated improvements in certain bone and renal laboratory parameters compared to those treated with Viread. Patients in the Vemlidy arm also experienced numerically higher rates of normalization of blood serum alanine aminotransferase (ALT) levels.

Vemlidy and Viread were generally well-tolerated by patients in both studies and discontinuations due to adverse events were 1% and 1.2%, respectively. The most commonly reported adverse events in both studies included headache, abdominal pain, fatigue, cough, nausea and back pain and occurred at similar rates in patients receiving either Vemlidy or Viread.

“Since the mid-1990s, Gilead has been working to improve and simplify care for people living with chronic hepatitis B,” said John Milligan, Ph.D., President and Chief Executive Officer of Gilead Sciences. “Vemlidy is the first medication approved to treat this disease in nearly a decade, and we are excited to offer a new, effective option to help advance long-term care for patients.”

Additional data on TAF will be presented at The Liver Meeting® 2016 in Boston.

U.S. Patient Support Program
Gilead’s U.S. Advancing Access® patient support program provides information regarding access and reimbursement coverage options to patients in the United States who need assistance with coverage for their medications, including Vemlidy.

Advancing Access conducts Vemlidy benefits investigations and provides patients with information regarding their insurance options. Further, the Vemlidy Co-pay Coupon Program offers co-pay assistance for eligible patients with private insurance who need assistance paying for out-of-pocket medication costs.

Information about how to enroll can be found at https://AdvancingAccessConsent.iassist.com/ or by calling 1-800-226-2056 between 9:00 a.m. and 8:00 p.m. (Eastern).

Global Availability

Gilead is committed to helping enable access to Vemlidy for all people in need, regardless of where they live or what resources they have. Since 2003, the company has operated a dedicated business unit focused on expanding access to medicines in lower-income countries. Gilead works with regional business partners on local country regulatory submissions to provide branded HBV drugs at reduced prices in 125 low- and middle-income countries. Gilead has also established licensing agreements with 19 generic drug manufacturers in India, South Africa and China, as well as the Medicines Patent Pool, granting them rights to produce and sell high-quality, low-cost generic versions of Gilead HBV medicines in 112 developing countries. Vemlidy is already an integrated component of the company’s generic licensing agreements, and with FDA approval, manufacturing partners may begin production and distribution of a generic version of this medicine.

IMPORTANT SAFETY INFORMATION

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

- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs.
- Discontinuation of anti-hepatitis B therapy, including VEMLIDY, may result in severe acute exacerbations of hepatitis B. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VEMLIDY. If appropriate, resumption of anti-hepatitis B therapy may be warranted.

Warnings and Precautions

- **Risk of Development of HIV-1 Resistance in HBV/HIV-1 Coinfected Patients:** Due to this risk, VEMLIDY alone is not recommended for the treatment of HIV-1 infection. Safety and efficacy of VEMLIDY have not been established in HBV/HIV-1 coinfected patients. HIV antibody testing should be offered to all HBV-infected patients before initiating therapy with VEMLIDY, and, if positive, an appropriate antiretroviral combination regimen that is recommended for HBV/HIV-1 coinfected patients should be used.
- **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 VEMLIDY, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue VEMLIDY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Renal monitoring: Assess serum creatinine, serum phosphorus, CrCl, urine glucose, and urine protein prior to initiating and during therapy in all patients as clinically appropriate.

Adverse Reactions
Most common adverse reactions (incidence ≥5%; all grades) were headache, abdominal pain, fatigue, cough, nausea and back pain.

**Drug Interactions**

- Coadministration of VEMLIDY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir and the risk of adverse reactions.
- Coadministration of VEMLIDY is not recommended with the following: oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, or St. John’s wort. Such coadministration is expected to decrease the concentration of tenofovir alafenamide, reducing the therapeutic effect of VEMLIDY. Drugs that strongly affect P-gp and BCRP activity may lead to changes in VEMLIDY absorption.

Consult the full prescribing information for VEMLIDY for more information on potentially significant drug interactions, including clinical comments.

**Dosage and Administration**

- **Dosage:** Adults; 1 tablet taken once daily with food.
- **Renal Impairment:** Not recommended in patients with CrCl <15 mL/min.
- **Hepatic Impairment:** Not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment.
- **Testing prior to initiation:** HIV infection.

**About Gilead Sciences**

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 worldwide. 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 Vemlidy for the treatment of chronic HBV. In addition, Gilead may be unable to obtain regulatory approval for Vemlidy for the treatment of chronic HBV from other regulatory authorities. 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 September 30, 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 statement.

**U.S. full prescribing information for Vemlidy, including BOXED WARNING, is available at** [www.gilead.com](http://www.gilead.com).

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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


Source: Gilead Sciences, Inc.