

European Commission Approves Truvada, a Once-a-Day Tablet Containing Gilead Sciences' Anti-HIV Drugs Emtriva and Viread

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 23, 2005--Gilead Sciences (Nasdaq:GILD) today announced that the European Commission has granted a Marketing Authorisation for Truvada(R) (emtricitabine and tenofovir disoproxil fumarate) in all 25 member states of the European Union. Truvada combines the company's anti-HIV medications Emtriva(R) (emtricitabine) and Viread(R) (tenofovir disoproxil fumarate) in one tablet, taken once a day in combination with other antiretroviral agents.

In the European Union, Truvada is indicated for the treatment of HIV-infected adults in combination with other antiretroviral agents. This indication is based on the demonstration of the benefit of the combination of emtricitabine and tenofovir disoproxil fumarate in antiretroviral therapy in treatment-naïve patients. As Truvada contains emtricitabine and tenofovir disoproxil fumarate, the guidance for physicians in the Truvada Summary of Product Characteristics (SmPC) is consistent with the guidance in the SmPCs of Emtriva and Viread. A European SmPC is similar to a product's Prescribing Information in the United States. For the approved indication for Truvada in the United States, based on the safety and efficacy of Emtriva and Viread evaluated independently as part of multidrug regimens, please see "About Truvada," below.

"Convenience is an increasingly important consideration in the construction of effective combination regimens for HIV," said Brian Gazzard, MD, Clinical Research Director, Chelsea and Westminster Hospital, London. "Because of their simplicity, co-formulated once-a-day drugs like Truvada are an important advance for doctors and patients interested in constructing more convenient combination HIV regimens."

Gilead submitted a Marketing Authorisation Application (MAA) for Truvada on March 12, 2004 under the centralized procedure. The European Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), gave a positive opinion of Truvada on November 18, 2004. This is the company's fourth antiviral to be granted marketing authorisation in Europe in three years.

"This approval marks an important milestone in the company's mission to advance the care of people living with HIV," said John C. Martin, PhD, President and CEO of Gilead. "By combining two of the three drugs necessary for triple-drug therapy into a single once-a-day tablet, Truvada provides an important option for doctors and patients looking to construct simplified combination regimens."

Both of the component drugs in Truvada belong to a class of anti-HIV medications called nucleoside reverse transcriptase inhibitors, or NRTIs, which work by blocking an enzyme crucial for viral replication. By interfering with the replication process, Truvada, when combined with other anti-HIV medications, can help lower the amount of HIV, or "viral load" in a patient's body and increase the number of immune system cells (called T cells or CD4 cells).

Both Truvada and Viread are available through Gilead's Access Program in 68 resource-limited countries, including all countries in Africa and 15 other United Nations defined "least developed countries," at no-profit pricing. The parent compound of Viread, tenofovir, was discovered through a collaborative research effort between Dr. Antonin Holy, Institute for Organic Chemistry and Biochemistry, Academy of Sciences of the Czech Republic (IOCB) in Prague and Dr. Erik DeClercq, Rega Institute for Medical Research, Katholic University in Leuven, Belgium. Emtriva was discovered by Dr. Raymond F. Schinazi, Dr. Dennis C. Liotta and Dr. Woo-Baeg Choi and licensed to Gilead by Emory University in 1996. Emory University and the inventors of both Viread and Emtriva, the components in Truvada, have agreed to waive their right to a royalty on sales of Truvada in the 68 Gilead Access Program countries to ensure the product can be offered at a no-profit price in parts of the world where the epidemic has hit the hardest.

It is important that patients be aware that HIV medications must be taken as part of combination regimens and that they do not cure HIV infection, nor do they reduce its transmission.

Important Safety Information from U.S. Prescribing Information for Truvada, Viread and Emtriva

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination with other antiretrovirals. Viread, Emtriva and Truvada are not indicated for the treatment of

chronic hepatitis B virus (HBV) infection and the safety and efficacy of these drugs has not been established in patients co-infected with HBV and HIV. Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued Viread or Emtriva. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue Viread, Emtriva or Truvada and are co-infected with HIV and HBV. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Changes in body fat have been observed in patients taking Viread, Emtriva, Truvada and other anti-HIV medicines. The cause and long term health effect of these conditions are unknown.

About Truvada

In the United States, Truvada is indicated in combination with other antiretroviral agents (such as non-nucleoside reverse transcriptase inhibitors or protease inhibitors) for the treatment of HIV-1 infection in adults. Safety and efficacy studies using Truvada tablets or using Emtriva and Viread in combination are ongoing.

Emtriva and Viread have each been studied as part of multi-drug regimens and have been found to be safe and effective. In clinical study 303 Emtriva and lamivudine (3TC) demonstrated comparable efficacy, safety and resistance patterns as part of multidrug regimens. These data, and those from study 903, in which lamivudine and tenofovir were used in combination, support the use of Truvada for the treatment of HIV-1 infection in treatment-naïve adults. In treatment-experienced patients, the use of Truvada should be guided by laboratory testing and treatment history.

There are no study results demonstrating the effect of Truvada on clinical progression of HIV-1, and it is not recommended that Truvada be used as a component of a triple nucleoside regimen.

Truvada should not be used with Emtriva or Viread, or other drugs containing lamivudine, including Combivir(R), Epivir(R), Epivir-HBV(R), Epzicom(TM) or Trizivir(R). Two-hundred eighty-three patients have received combination therapy with Emtriva and Viread with either a non-nucleoside reverse transcriptase inhibitor or protease inhibitor for 24 to 48 weeks in ongoing clinical studies. Based on these limited data, no new patterns of adverse events were identified and there was no increased frequency of established toxicities. For additional safety information about Emtriva or Viread in combination with other antiretroviral agents, please see "About Emtriva" and "About Viread," below.

About Viread

In the United States, Viread is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. This indication is based on analyses of plasma HIV-1 RNA levels and CD4 cell counts in controlled studies of Viread in treatment-naïve adults and in treatment-experienced adults. There are no study results demonstrating the effect of Viread on clinical progression of HIV-1. The use of Viread should be considered for treating adult patients with HIV-1 strains that are expected to be susceptible to tenofovir as assessed by laboratory testing or treatment history.

Drug interactions have been observed when didanosine, atazanavir or lopinavir/ritonavir is co-administered with Viread and dose adjustments may be necessary. Data are not available to recommend a dose adjustment of didanosine for patients weighing less than 60 kg. Patients on atazanavir or lopinavir/ritonavir plus Viread should be monitored for Viread-associated adverse events which may require discontinuation. When co-administered with Viread, it is recommended that atazanavir 300 mg be given with ritonavir 100 mg. Atazanavir without ritonavir should not be co-administered with Viread.

Renal impairment, including serious cases, has been reported. Renal impairment occurred most often in patients with underlying systemic or renal disease or in patients taking concomitant nephrotoxic agents, though some cases have appeared in patients without identified risk factors. Decreases in bone mineral density (BMD) at the lumbar spine and hip have been seen with the use of Viread. The clinical significance of changes in BMD and biochemical markers is unknown and follow-up is continuing to assess long-term impact. The most common adverse events and those occurring in more than 5 percent of patients receiving Viread with other antiretroviral agents in clinical trials include asthenia, pain, abdominal pain, headache, nausea, diarrhea, vomiting, rash (rash, pruritis, maculopapular rash, urticaria, vesiculobullous rash and pustular rash), flatulence, dizziness and depression. Less than 1 percent of patients discontinued participation because of gastrointestinal events.

About Emtriva

In the United States, Emtriva is indicated, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults. This indication is based on analyses of plasma HIV-1 RNA levels and CD4 cell counts from controlled studies of 48 weeks duration in antiretroviral-naive patients and antiretroviral-treatment-experienced patients who were virologically suppressed on an HIV treatment regimen. In antiretroviral-treatment-experienced patients, the use of Emtriva may be considered for adults with HIV strains that are expected to be susceptible to Emtriva as assessed by genotypic or phenotypic testing.

Adverse events that occurred in more than 5 percent of patients receiving Emtriva with other antiretroviral agents in clinical trials include abdominal pain, asthenia (weakness), headache, diarrhea, nausea, vomiting, dizziness and rash (rash, pruritis, maculopapular rash, urticaria, vesiculobullous rash, pustular rash and allergic reaction). Approximately 1 percent of patients discontinued participation because of these events. All adverse events were reported with similar frequency in Emtriva and control treatment groups with the exception of skin discoloration which was reported with higher frequency in the Emtriva treated group. Skin discoloration, manifested by hyperpigmentation on the palms and/or soles, was generally mild and asymptomatic. The mechanism and clinical significance are unknown.

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. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Australia.

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. These risks and uncertainties could cause actual results to differ materially from those referred to in the forward-looking statements. Risks are described in detail in the Gilead Annual Report on Form 10-K for the year ended December 31, 2003 and in Gilead's Quarterly Reports on Form 10-Q, all of which are on file 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.

Truvada, Emtriva and Viread are registered trademarks of Gilead Sciences, Inc.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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