European CPMP Gives Positive Opinion on Emtriva, Gilead's New Once-Daily Treatment for HIV

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FOSTER CITY, Calif.--(BUSINESS WIRE)--July 24, 2003--Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the European Union's Committee for Proprietary Medicinal Products (CPMP), the scientific committee of the European Medicines Evaluation Agency (EMEA), has recommended granting Marketing Authorisation for the company's new once-daily medication for HIV, Emtriva(TM) (emtricitabine, 200 mg hard capsule and 10 mg/mL oral solution), in the 15 member states of the European Union.

The CPMP's recommended indication for Emtriva is for the treatment of HIV-infected adults and children in combination with other antiretroviral agents. This indication is based on studies in treatment-naive patients and treatment-experienced patients with stable virological control. There is no experience with the use of Emtriva in patients who are failing their current regimen or who have failed multiple regimens. When deciding on a new regimen for patients who have failed an antiretroviral regimen, careful consideration should be given to the patterns of mutations associated with different medicinal products and the treatment history of the individual patient. Where available, resistance testing may be appropriate.

The European Commission is expected to act on the CPMP recommendation by late 2003. The Marketing Authorisation Application (MAA) for Emtriva was submitted for review under the centralized procedure in January 2003 by Triangle Pharmaceuticals, which was acquired by Gilead Sciences later that month. The U.S. Food and Drug Administration (FDA) granted marketing approval for Emtriva in the United States on July 2 of this year.

"As people are living with and being treated for HIV over longer periods of time, there is a vital need for antiretroviral treatments with a profile like Emtriva's that can help patients manage the disease with fewer pills and, most importantly, reduced side effects," said Dr. Francois Raffi of the Centre Hospitalier Universitaire de Nantes, France. "The European regulators' rapid review and positive recommendation of this application brings us a step closer to the availability of another effective HIV drug in Europe."

Worldwide, it is estimated that 42 million people are living with HIV/AIDS. In Western Europe, an estimated 570,000 people are infected with the virus, an increase of 10 percent compared to the 520,000 who were infected in 2000.

"We are pleased that the members of the CPMP have delivered a positive opinion on Emtriva so quickly," said John C. Martin, PhD, President and CEO, Gilead Sciences. "We will continue to work closely with the regulatory authorities to facilitate approval for Emtriva in order to ensure that this important new once-daily treatment option becomes available for people with HIV in Europe."

The CPMP's positive opinion for Emtriva is the second that Gilead has received from the Committee for a new HIV treatment. Viread(R) (tenofovir disoproxil fumarate), the company's first antiretroviral for HIV, received a positive CPMP recommendation in October 2001 and was subsequently granted Marketing Authorisation by the European Commission in February 2002. Additionally, Hepsera(R) (adefovir dipivoxil 10 mg), the company's product for chronic hepatitis B, received a positive recommendation in November 2002 and was granted Marketing Authorisation in March 2003.

About Emtriva

Emtriva is dosed once daily and can be taken with or without food. In the United States, Emtriva is indicated, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults. Emtriva works by blocking reverse transcriptase, an enzyme crucial for HIV replication.

In controlled clinical studies, Emtriva has been shown to effectively suppress HIV replication when taken in combination with other antiretroviral medications. Emtriva has reduced the level of HIV in the blood for up to 48 weeks among patients starting antiretroviral treatment for the first time, as well as in treatment-experienced individuals with stable virological control.

Safety Profile

More than 2000 HIV-infected adults have been treated with Emtriva for periods of 10 days to 200 weeks in Phase I, II and III clinical trials. Assessment of adverse events (without regard to relationship to study drug) is based on pooled data from two Phase

III studies in which 571 treatment-naive and 440 treatment-experienced patients received Emtriva (n=580) or a comparator drug (n=431) for 48 weeks. The most common adverse events that occurred in patients receiving Emtriva were headache, diarrhea, nausea and rash, which were generally of mild to moderate severity. Approximately one percent of patients discontinued participation in the clinical studies due to 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 (excess pigmentation) on the palms and/or soles, was generally mild and asymptomatic. The mechanism and clinical significance of this adverse event are unknown.

A separate analysis evaluated adverse drug reactions with at least a possible relationship to study drug. Assessment of these adverse drug reactions is based on data from three studies in adults (n=1479) and two pediatric studies (n=114). In the adult studies, 1039 treatment-naive and 440 treatment-experienced patients received Emtriva (n=814) or comparator medicinal product (n=665) for 48 weeks in combination with other antiretroviral medicinal products. In the pediatric studies, treatment-naive (n=83) and treatment-experienced (n=31) pediatric patients aged 4 months to 18 years were treated with Emtriva in combination with other antiretroviral agents. The most common adverse reactions observed include headache, diarrhea, nausea and elevations in creatine kinase.

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. In chronic hepatitis B infected patients exacerbations of hepatitis B have been reported after discontinuation of Emtriva, and patients co-infected with HIV and HBV should be closely monitored after stopping Emtriva treatment. Patients with renal impairment should be carefully monitored and may require dose interval adjustments (using Emtriva 200 mg hard capsule) or dose reduction (using Emtriva 10 mg/mL oral solution).

About Gilead

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases worldwide. The company has seven marketed products and focuses its research and clinical programs on anti-infectives. Headquartered in Foster City, CA, Gilead has operations in the United States, 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 that could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned that the CPMP opinion is not binding upon the EMEA, that Emtriva remains an investigational compound in the European Union that has not been determined to be safe and effective in humans for its intended use, that the European Commission may delay official action beyond late 2003, and that there remain a number of risks related to regulatory approval of Emtriva in the European Union. These and other risks are described in detail in the Gilead Annual Report on Form 10-K for the year ended December 31, 2002 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.

Emtriva is a trademark and Viread and Hepsera are registered trademarks of Gilead Sciences, Inc.

For more information on Emtriva, please call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235) or visit www.gilead.com.

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