Phase III Data Show Emtricitabine Maintains Viral Load Suppression as Part of Once-Daily, Protease-Sparing Anti-HIV Regimen

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BOSTON, Feb 11, 2003 (BUSINESS WIRE) --

48-Week Data from Alize Trial Presented Today at 10th Conference on Retroviruses and Opportunistic Infections

French researchers presented new 48-week data from a Phase III clinical trial today. These data demonstrate that emtricitabine (FTC), an investigational once-daily nucleoside reverse transcriptase inhibitor (NRTI), suppresses HIV when taken as part of a once-daily, protease inhibitor (PI)-sparing antiretroviral regimen. Emtricitabine is being developed by Triangle Pharmaceuticals, which was acquired by Gilead Sciences (Nasdaq:GILD) in January 2003. Dr. Jean-Michel Molina presented the 48-week results of the ANRS 099 Alize trial (Abstract #551) at the 10th Conference on Retroviruses and Opportunistic Infections in Boston, Massachusetts.

The ANRS 099 Alize trial is an ongoing three-year, open-label, multicenter study involving 355 patients who at baseline had to have HIV RNA less than 400 copies/mL while receiving PI-based antiretroviral therapy. The median duration of PI therapy was 35 months, and the median CD4 cell count was 540 cells/mm3. Patients were randomized (1:1) to continue their stable PI-based regimen or switch to an entirely once-daily regimen of emtricitabine, didanosine (another NRTI) and efavirenz (a non-nucleoside reverse transcriptase inhibitor, or NNRTI).

"These data suggest that switching to a once-daily, PI-sparing antiretroviral regimen including emtricitabine is effective in maintaining suppression of HIV infection," said Dr. Molina. "While both arms of the study demonstrated comparable and durable antiviral response, the data may be of particular interest to physicians and patients who now have the alternative to use a convenient once-daily HAART regimen with a low pill burden."

Study Results

At 48 weeks, 94 percent of patients receiving the once-daily regimen of emtricitabine, didanosine and efavirenz had HIV RNA levels (viral load) less than 400 copies/mL, compared to 92 percent randomized to continue therapy in the PI-based arm (intent to treat population, assays performed at local laboratories at investigational centers). When all the samples were analyzed with a more sensitive assay at a central laboratory, the proportion of patients with HIV RNA less than 50 copies/mL at week 48 was significantly higher in the once-daily treatment group. Ninety-five percent of patients in the once-daily group achieved this result, compared to 87 percent in the PI-based arm (p=0.01). The median CD4 cell count increase was comparable in both arms, with an increase of 21 cells/mm3 for patients on the once-daily regimen and 13 cells/mm3 for those in the PI-based group.

The discontinuation rate in the study was similar between the two arms, with 10.1 and 12.4 percent of patients in the once-daily arm and PI-based arm discontinuing, respectively. Additionally, patients switching to once-daily therapy with emtricitabine, didanosine and efavirenz experienced an increase of 7.7 mg/dL in fasting high-density lipoprotein cholesterol (HDL - or "good" cholesterol), as compared to no change in the PI-based arm (p less than 0.0001). In clinical studies of emtricitabine, the most common adverse events observed have been infection, diarrhea, headache, nausea and rash.

"These results suggest that emtricitabine will play a key role in future anti-HIV therapy, in particular when given with other once-daily therapies such as Gilead's existing HIV medication, Viread(R) (tenofovir disoproxil fumarate)," said John C. Martin, PhD, President and Chief Executive Officer, Gilead Sciences. "Emtricitabine's ability to control HIV replication in different treatment combinations confirms our confidence in this compound. Today's HIV patients and physicians are demanding convenient, once-daily treatment regimens with minimal side effects. We expect that, together with Viread, emtricitabine will be important in meeting this need."

About Emtricitabine

Emtricitabine is a once-daily nucleoside reverse transcriptase inhibitor currently in Phase III testing for the treatment of HIV and chronic hepatitis B. Emtricitabine is chemically related to lamivudine (3TC), the most commonly-prescribed drug for HIV infection. In vitro, the drug has been shown to be four- to ten-fold more potent than lamivudine.

Applications for marketing approval of emtricitabine for the treatment of HIV were submitted to U.S. and European regulatory authorities in September and December of 2002, respectively, by Triangle Pharmaceuticals. Emtricitabine has not been determined safe or efficacious for the treatment of HIV or chronic hepatitis B by the FDA or any other regulatory agency.

About Gilead Sciences

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 six 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. These risks and uncertainties include the risk that we will not continue to observe the safety and efficacy data observed in this clinical trial through longer periods of treatment and in other trials, the risk that regulatory authorities may disagree with our interpretation of these data, the risk that we may not be granted marketing approval for emtricitabine or may not be able to promptly launch emtricitabine following any such approval, and the risk that we may not be able to successfully combine emtricitabine with Viread. These and other risks associated with the development of investigational therapeutics are described in detail in the Gilead Annual Report on Form 10-K for the year ended December 31, 2001 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.

Note to Editors: Viread is a registered trademark of Gilead Sciences, Inc.

For more information on emtricitabine or Gilead, 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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