96-Week Data from Gilead's Study 934 Comparing Viread(R) and Emtriva(R) to Combivir(R) Both in Combination with Sustiva(R) Presented at XVI International AIDS Conference

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TORONTO--(BUSINESS WIRE)--Aug. 14, 2006--Gilead Sciences, Inc. (Nasdaq:GILD) today announced the presentation of 96-week data from an ongoing clinical trial (Study 934) comparing a once-daily regimen of Viread(R) (tenofovir disoproxil fumarate), Emtriva(R) (emtricitabine) and Sustiva(R) (efavirenz) to a twice-daily regimen of Combivir(R) (lamivudine/zidovudine) with Sustiva once daily in treatment-naive adults with HIV. Viread, Emtriva and Sustiva are available in the United States as the fixed-dose product ATRIPLA(TM) (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg), through a U.S. joint venture between Bristol-Myers Squibb and Gilead Sciences. ATRIPLA is currently approved in the United States for the treatment of HIV-1 infection in adults.

Study 934 is an ongoing Phase III, open-label clinical trial in the United States and Europe. Ninety-six week data are being presented by Joel Gallant, MD, Johns Hopkins University School of Medicine, Baltimore, at the XVI International AIDS Conference taking place August 13-18 in Toronto (Poster # TUPE0064). Data from this analysis have not been reviewed by the U.S. Food & Drug Administration.

"We now have two-year data suggesting that the once-daily regimen contained in Atripla is convenient and tolerable for many patients, and can provide effective, durable viral suppression over the long term," said Dr. Gallant. "Long-term studies like this one are important to demonstrate the durability of antiretroviral regimens, as patients are beginning to initiate treatment earlier and remain on treatment for longer periods of time."

Study 934

Study 934 is a Phase III, randomized, open-label, active-controlled, multicenter, non-inferiority study that enrolled 517 HIV-infected patients in the United States and Europe. The study's primary endpoint was at 48 weeks and the study is continuing through 144 weeks. The prespecified primary efficacy population included all patients who received at least one dose of study medication and who did not have NNRTI resistance at baseline (n=487). Participants in one arm of the study received Viread 300 mg, Emtriva 200 mg and Sustiva 600 mg, all dosed once daily. Patients in the comparator arm received Combivir twice daily and Sustiva 600 mg once daily. At study entry, patients had not previously received antiretroviral therapy and had HIV RNA (viral load) greater than 10,000 copies/mL.

After 96 weeks of treatment (n=463), 75 percent of patients in the Viread/Emtriva/Sustiva arm compared to 62 percent of patients in the Combivir/Sustiva arm achieved and maintained HIV RNA less than 400 copies/mL using the Time to Loss of Virologic Response algorithm (TLOVR) (p=0.004; 95% CI, +4% to +21%). Sixty-seven percent of patients in the Viread/Emtriva/Sustiva arm compared to 61 percent of patients in the Combivir/Sustiva arm achieved and maintained HIV RNA less than 50 copies/mL using the TLOVR algorithm (p=0.16; 95% CI, -2% to +15%). Patients receiving Viread/Emtriva/Sustiva experienced a greater mean increase from baseline in CD4 cell counts at week 96 compared to those receiving Combivir/Sustiva (270 vs. 237 cells/mm3; p=0.036).

Genotypic resistance analyses were performed on all patients from the primary efficacy population who either had confirmed plasma HIV RNA greater than 400 copies/mL or discontinued study drug early. Through 96 weeks, no patients in either arm of the study developed the K65R mutation, which is associated with reduced susceptibility to Viread. Fewer Viread/Emtriva/Sustiva patients developed the M184V/I mutation, which is associated with resistance to Emtriva and to the lamivudine component of Combivir (2 patients, vs. 9 in the Combivir/Sustiva arm; p=0.036).

After 96 weeks of treatment, a significantly greater percentage of patients in the Combivir/Sustiva group experienced adverse events that resulted in discontinuation of study medications compared to the Viread/Emtriva/Sustiva arm (11 vs. 5 percent, respectively; p=0.023). The most common cause of discontinuation related to study drug in the Combivir/Sustiva arm was anemia (14 patients, vs. 0 in the Viread/Emtriva/Sustiva arm; p less than 0.001), and in the Viread/Emtriva/Sustiva

arm was rash, which occurred in 4 patients.

Renal safety was similar and renal function remained stable through 96 weeks in the two groups. No patient discontinued study medication due to renal events. Patients receiving Viread/Emtriva/Sustiva had a significantly greater median increase from baseline in weight compared to patients receiving Combivir/Sustiva (2.7 kg vs. 0.5 kg, respectively; p less than 0.001). In addition, in a subset of patients with 48- and 96-week data, a significant median decrease in limb fat was seen in the Combivir/Sustiva arm (decrease from 6.0 to 5.5 kg; n=44; p=0.001) while a significant median increase was observed in the Viread/Emtriva/Sustiva arm (increase from 7.4 to 8.1 kg; n=49; p=0.01).

Important Product Safety Information

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.

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

It is important for patients to be aware that anti-HIV medicines including ATRIPLA, Viread and Emtriva do not cure HIV infection or AIDS, nor have they been shown to reduce the risk of transmission of HIV to others.

Additional Important Information About ATRIPLA

ATRIPLA is indicated for use alone as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults.

ATRIPLA is contraindicated for use with astemizole, cisapride, midazolam, triazolam, ergot derivatives, or voriconazole. Concomitant use of ATRIPLA and St. John's wort (Hypericum perforatum) or St. John's wort-containing products is not recommended. Since ATRIPLA contains efavirenz, emtricitabine and tenofovir disoproxil fumarate, it should not be coadministered with Sustiva, Emtriva, Viread, or Truvada. Due to similarities between emtricitabine and lamivudine, ATRIPLA should not be coadministered with drugs containing lamivudine, including Combivir, Epivir(R), Epivir-HBV(R), Epzicom(TM), or Trizivir(R).

Serious psychiatric adverse experiences, including severe depression (2.4%), suicidal ideation (0.7%), nonfatal suicide attempts (0.5%), aggressive behavior (0.4%), paranoid reactions (0.4%) and manic reactions (0.2%) have been reported in patients treated with efavirenz. In addition to efavirenz, factors identified in a clinical study that were associated with an increase in psychiatric symptoms included a history of injection drug use, psychiatric history and use of psychiatric medication. There have been occasional reports of suicide, delusions and psychosis-like behavior, but it could not be determined if efavirenz was the cause. Patients with serious psychiatric adverse experiences should be evaluated immediately to determine whether the risks of continued therapy outweigh the benefits. Fifty-three percent of patients reported central nervous system symptoms including dizziness (28.1%), insomnia (16.3%), impaired concentration (8.3%), somnolence (7.0%), abnormal dreams (6.2%) and hallucinations (1.2%) when taking efavirenz compared to 25% of patients receiving control regimens. These symptoms usually begin during the first or second day of therapy and generally resolve after the first two to four weeks of therapy. After four weeks of therapy, the prevalence of central nervous system symptoms of at least moderate severity ranged from 5% to 9% in patients treated with regimens containing efavirenz. Nervous system symptoms are not predictive of the less frequent psychiatric symptoms.

ATRIPLA should not be given to patients with creatinine clearance below 50 mL/min. Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported in

association with the use of tenofovir disoproxil fumarate, most often in patients with underlying systemic or renal disease, or in patients taking concomitant nephrotoxic agents. Some cases have occurred in patients with no identified risk factors. ATRIPLA should be avoided with concurrent or recent use of a nephrotoxic agent.

ATRIPLA may cause fetal harm when administered during the first trimester to a pregnant woman. Women should not become pregnant or breastfeed while taking ATRIPLA. Barrier contraception must always be used in combination with other methods of contraception such as oral or other hormonal contraceptives. If the patient becomes pregnant while taking ATRIPLA, she should be apprised of the potential harm to the fetus.

Mild to moderate rash is a common side effect of efavirenz. In controlled clinical trials, 26% of patients treated with efavirenz experienced new-onset skin rash compared with 17% of patients treated in control groups. Skin discoloration, associated with emtricitabine, may also occur. ATRIPLA should be discontinued in patients developing severe rash associated with blistering, desquamation, mucosal involvement, or fever. Liver enzymes should be monitored in patients with known or suspected hepatitis B or C and when ATRIPLA is administered with ritonavir or other medications associated with liver toxicity. Decreases in bone mineral density (BMD) have been seen with tenofovir disoproxil fumarate. Use ATRIPLA with caution in patients with a history of seizures. Convulsions have been observed in patients receiving efavirenz, generally in the presence of known medical history of seizures. Redistribution and/or accumulation of body fat have been observed in patients receiving antiretroviral therapy. Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including the components of ATRIPLA.

Coadministration of ATRIPLA and atazanavir is not recommended due to concerns regarding decreased atazanavir concentrations. Patients on lopinavir/ritonavir plus ATRIPLA should be monitored for tenofovir-associated adverse events. ATRIPLA should be discontinued in patients who develop tenofovir-associated adverse events. Coadministration of ATRIPLA and didanosine should be undertaken with caution. Patients receiving this combination should be monitored closely for didanosine-associated adverse events. See full prescribing information for complete list of drug-drug interactions.

In a large controlled clinical trial (Study 934), adverse events observed in greater than or equal to 5% of patients in the Viread/Emtriva/Sustiva group include dizziness, nausea, diarrhea, fatigue, headache, and rash.

The dose of ATRIPLA is one tablet once daily taken orally on an empty stomach. Dosing at bedtime may improve the tolerability of nervous system symptoms.

About Viread

In the United States, Viread is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. Viread should not be used in combination with Truvada.

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 and 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 cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported among patients taking Viread. 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 effects of Viread-associated changes in BMD and biochemical markers on long-term bone health and future fracture risk are unknown. Redistribution and/or accumulation of body fat have been observed in patients receiving antiretroviral therapy. Immune reconstitution syndrome has been reported in patients

treated with combination antiretroviral therapy including Viread.

The most common adverse events among patients receiving Viread with other antiretroviral agents in clinical trials were mild to moderate gastrointestinal events and dizziness. Moderate to severe adverse events occurring in more than 5 percent of patients receiving Viread included rash (rash, pruritis, maculopapular rash, urticaria, vesiculobullous rash and pustular rash), headache, pain, diarrhea, depression, back pain, fever, nausea, abdominal pain, asthenia and anxiety (Study 903). Less than 1 percent of patients discontinued participation because of gastrointestinal events (Study 907).

The parent compound of Viread 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.

About Emtriva

In the United States, Emtriva is indicated, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in patients over three months of age. 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.

Redistribution and/or accumulation of body fat have been observed in patients receiving antiretroviral therapy. Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy including Viread. For pediatric patients over three months of age, the adverse event profile observed during clinical trials was similar to that of adult patients, with the exception of anemia and a higher frequency of hyperpigmentation.

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. Visit Gilead on the World Wide Web at www.gilead.com.

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 and regulatory agencies may not see advantages of ATRIPLA over other antiretrovirals and may therefore be reluctant to prescribe the product. 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 the Gilead Annual Report on Form 10-K for the year ended December 31, 2005, 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.

Full U.S. prescribing information for ATRIPLA is available at www.atripla.com.

Full prescribing information for Viread and Emtriva is available at www.gilead.com.

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