Gilead Announces 48-Week Data Evaluating Switching from Combivir(R) To Truvada(R) Among Virologically-Suppressed HIV Patients

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-- Results From Phase III 'SWEET' Study Presented at the 11th European AIDS Conference --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 29, 2007--Gilead Sciences, Inc. (Nasdaq:GILD) today announced 48-week data from a Phase III clinical trial evaluating virologically-suppressed patients with HIV who switched from treatment with twice-daily Combivir(R) (lamivudine/zidovudine) to treatment with Gilead's once-daily Truvada(R) (emtricitabine and tenofovir disoproxil fumarate) as part of their combination drug therapy. In the SWEET (Simplification With Easier Emtricitabine and Tenofovir) study, patients who switched from Combivir to Truvada, both in combination with once-daily Sustiva(R) (efavirenz), experienced improvements in a number of treatment-related side effects. Patients in both study arms maintained virological suppression at 48 weeks. The data were presented at the 11th European AIDS Conference (EACS), held October 24-27 in Madrid, Spain.

"As HIV patients live longer and remain on therapy for extended periods of time, the long-term side effect profile of treatment is increasingly more important," said Martin Fisher, MD, Brighton and Sussex University Hospitals, Brighton, United Kingdom and the principal investigator for the SWEET study. "Data from this study indicate that patients on long-term Combivir therapy without clinical lipoatrophy may benefit from switching to Truvada, as virological control can be maintained and limb fat loss and recovery may be improved. These data support the new EACS 2007 guidelines regarding proactive switching."

New European HIV treatment guidelines issued this week at EACS list Truvada among the recommended components of a first-line treatment regimen for antiretroviral naive patients. Combivir, previously recommended as a first-line treatment option, is now listed as an alternative treatment option.

In the United States, the components of Truvada and Sustiva are available in a fixed-dose combination tablet called Atripla(R) (efavirenz 600mg / emtricitabine 200mg / tenofovir disoproxil fumarate 300 mg). Atripla is currently the first and only once-daily single tablet regimen approved for the treatment of HIV-1 infection in adults in the United States for use either as stand-alone therapy or in combination with other antiretroviral agents. On October 18, 2007, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) recommended that Atripla be approved for use in the European Union. A final decision on Atripla by the European Commission is expected by the end of the year.

About The SWEET Study

SWEET was a 48-week, multicenter, prospective, open-label study evaluating 250 HIV-infected patients. At study entry, patients received a treatment regimen of Combivir and Sustiva and were virologically controlled with HIV RNA of less than 50 copies/mL for the last two consecutive testings and less than 400 copies/mL for more than three months. Of the 250 patients enrolled in the study, 234 received at least one dose of study drug. Subjects were randomized 1:1 to continue with a regimen of Combivir and Sustiva (n=117) or switch to a regimen of Truvada and Sustiva (n=117). Baseline characteristics were well matched between study arms. The median prior use of Combivir among patients was 36 months. Among patients who switched to Truvada and Sustiva, 88 percent were suppressed to less than 50 copies/mL at 48 weeks, compared to 85 percent of patients who continued with Combivir (intent-to-treat, missing = failure analysis; 95% CI: -6% to +11%; p=0.70). In addition, median CD4 counts remained comparable between the study arms.

Limb fat was measured using DEXA scans in a subset of 100 study participants, of whom 74 had both baseline and 48-week data available. In this sub-study, a median increase in limb fat of 0.21 kg was observed among patients who switched to Truvada and a median decrease of 0.14 kg was observed among patients who continued on Combivir (p=0.025). Differences in limb fat were more pronounced among patients who had less experience with AZT

(zidovudine).

At week 48, a median increase in hemoglobin of 0.5 g/dL was observed among Truvada patients and a median decrease of 0.1 g/dL was observed among those taking Combivir (p less than 0.001). Twenty-two percent of patients who switched to Truvada (n=22) experienced an increase in hemoglobin greater than 1 g/dL at 48 weeks compared to 2 percent of Combivir patients (n=2). Conversely, 9 percent of patients who remained on Combivir (n=8) experienced a reduction in hemoglobin greater than 1 g/dL, compared to 2 percent of patients who switched to Truvada (n=2).

Truvada patients in the study also experienced improvements across a number of lipid parameters. After 48 weeks of treatment, fasting total cholesterol fell by a median of 0.22 mmol/L (8.46 mg/dl) among Truvada patients, compared to a reduction of 0.06 mmol/L (2.30 mg/dl) among Combivir patients (p=0.23; Truvada vs. Combivir comparison). Fasting triglycerides fell by a median of 0.17 mmol/L (15.45 mg/dl) among Truvada patients, but increased by 0.04 mmol/L (3.63 mg/dl) among those who continued treatment with Combivir (p=0.11; Truvada vs. Combivir comparison).

Renal function remained within normal ranges in both treatment arms after 48 weeks of treatment, as measured by creatinine clearance (Cockroft-Gault) and estimated glomerular filtration rate (MDRD). Median creatinine increased by 3 umol/L (less than 0.01 mg/dl) among Truvada patients (p less than 0.001), and declined by 1 umol/L (less than 0.01 mg/dl) among patients in the Combivir group (p=0.57).

Five percent of Combivir patients and 3 percent of Truvada patients discontinued study drug due to adverse events. These included dizziness, insomnia, nausea, depression and sleep disorder in the Truvada arm and angiosarcoma, pulmonary embolism, pulmonary hypertension, weight loss of arms and legs, syncope, worsening of lipoatrophy and depression in the Combivir arm.

Important Product Safety Information About Truvada and Atripla

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. Truvada and Atripla are not approved for the treatment of chronic hepatitis B virus (HBV) infection and their safety and efficacy 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(R) (tenofovir disoproxil fumarate) or Emtriva(R) (emtricitabine), which are components of Truvada and Atripla. In some of these patients treated with Emtriva, the exacerbations of hepatitis B were associated with liver decompensation and liver failure. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are co-infected with HIV and HBV and discontinue Truvada or Atripla. If appropriate, initiation of anti-hepatitis B treatment may be warranted.

It is important for patients to be aware that anti-HIV medicines including Truvada and Atripla do not cure HIV infection or AIDS and do not reduce the risk of transmitting HIV to others.

Additional Important Information About Truvada

Truvada is a fixed-dose combination tablet containing 200 mg of emtricitabine (Emtriva) and 300 mg of tenofovir disoproxil fumarate (Viread). 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.

It is not recommended that Truvada be used as a component of a triple nucleoside regimen. Truvada should not be coadministered with Atripla, Emtriva, Viread or lamivudine-containing products, including Combivir (lamivudine/zidovudine), Epivir(R) or Epivir-HBV(R) (lamivudine), Epzicom(TM) (abacavir sulfate/lamivudine) or Trizivir(R) (abacavir sulfate/lamivudine/zidovudine). In treatment-experienced patients, the use of Truvada should be guided by laboratory testing and treatment history.

Emtricitabine and tenofovir are principally eliminated by the kidneys. 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 Viread, a component of Truvada. It is recommended that creatinine clearance be calculated in all patients prior to initiating therapy with Truvada and as clinically appropriate during therapy. Routine monitoring of calculated creatinine clearance and serum phosphorous should be performed in patients at risk for renal impairment. Dosing interval adjustment and close monitoring of renal function are recommended in all patients with creatinine clearance of 30-49 ml/min. Truvada should be avoided with concurrent or recent use of a nephrotoxic agent.

No drug interaction studies have been conducted using Truvada. The U.S. package insert advises that co-administration of Truvada and didanosine should be undertaken with caution. Patients should be monitored closely for didanosine-associated adverse events and didanosine should be discontinued if these occur. Patients on atazanavir and lopinavir/ritonavir plus Truvada should be monitored for Truvada-associated adverse events and Truvada should be discontinued if these occur. When co-administered with Truvada, it is recommended that atazanavir be given with ritonavir 100 mg. Atazanavir without ritonavir should not be co-administered with Truvada.

Decreases in bone mineral density (BMD) at the lumbar spine and hip have been seen with the use of Viread. The effect on long-term bone health and future fracture risk is unknown. Cases of osteomalacia (associated with proximal renal tubulopathy) have been reported in association with the use of Viread.

Changes in body fat have been observed in patients taking anti-HIV medicines. The mechanism and long-term health effect of these conditions are unknown. Immune Reconstitution Syndrome has been reported in patients treated with combination therapy, including Viread and Emtriva.

Treatment-emergent adverse events occurring in at least 3 percent of patients receiving Viread and Emtriva in Study 934 included dizziness (8%), diarrhea (7%), nausea (8%), fatigue (7%), sinusitis (4%), upper respiratory tract infections (3%), nasopharyngitis (3%), somnolence (3%), headache (5%), dizziness (8%), depression (4%), insomnia (4%), abnormal dreams (4%) and rash (5%).

Skin discoloration has been reported with higher frequency among Emtriva-treated patients. Skin discoloration, manifested by hyperpigmentation on the palms and/or soles was generally mild and asymptomatic. The mechanism and clinical significance are unknown.

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. The inventors of Viread have agreed to waive their right to a royalty on sales of Viread and Truvada in the Gilead Access Program countries to ensure the product can be offered at cost in parts of the world where the epidemic has hit the hardest.

For complete prescribing information for Truvada, visit www.truvada.com. For full prescribing information outside of the United States, physicians should consult their local product labeling.

Additional Important Information About Atripla

In the United States, 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 contains the components Truvada (emtricitabine and tenofovir disoproxil fumarate) and Sustiva (efavirenz), co-formulated as a single tablet. As such, the important safety information appearing in the above Truvada section also applies to Atripla, in addition to the following important product information.

As a fixed-dose regimen of Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine) and Sustiva (efavirenz), Atripla should not be coadministered with Viread, Emtriva, Truvada (emtricitabine and tenofovir disoproxil fumarate) or Sustiva. Due to similarities between Emtriva and lamivudine, Atripla should not be coadministered with drugs containing

lamivudine, including Combivir (lamivudine/zidovudine), Epivir or Epivir-HBV (lamivudine), Epzicom (abacavir sulfate/lamivudine) or Trizivir (abacavir sulfate/lamivudine/zidovudine).

Atripla should not be taken with Hismanal(R) (astemizole), Vascor(R) (bepridil), Propulsid(R) (cisapride), Versed(R) (midazolam), Orap(R) (pimozide), Halcion(R) (triazolam), ergot medicines (for example, Wigraine(R) and Cafergot(R)), or Vfend(R) (voriconazole) due to a contraindication with efavirenz. Use of Atripla with St. John's wort (Hypericum perforatum) or St. John's wort-containing products is not recommended. This list of medicines is not complete. Patients should discuss all prescription and non-prescription medicines, vitamin and herbal supplements, or other health preparations they are taking or plan to take with their healthcare provider.

Atripla should not be given to patients with creatinine clearance less than 50 ml/min.

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, a component of Atripla. 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 death by 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. Patients should tell their doctor if they have a history of mental illness or are using drugs or alcohol.

Fifty-three percent of patients in clinical studies have 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 percent 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 percent in patients treated with regimens containing efavirenz. Nervous system symptoms are not predictive of the less frequent psychiatric symptoms.

Women should not become pregnant or breastfeed while taking Atripla. Serious birth defects have been seen in children of women treated with efavirenz during pregnancy. Women must use a reliable form of barrier contraception, such as a condom, even if they also use other methods of birth control.

Rash is a common side effect that usually goes away without any change in treatment. Rash may be a serious problem in some children.

Patients with liver disease may require the healthcare provider to check liver function or check drug levels in the blood.

Atripla should be used with caution in patients with a history of seizures. Convulsions have been observed in patients receiving efavirenz, generally in the presence of a known medical history of seizures.

Invirase(R) (saquinavir) should not be used as the only protease inhibitor in combination with Atripla.

The most significant adverse events observed in patients treated with Sustiva are nervous system symptoms, psychiatric symptoms and rash. The most common adverse events (at least 5%) observed in clinical studies with Sustiva include fatigue, pain, dizziness, headache, insomnia, impaired concentration, nausea, vomiting, diarrhea, depression, rash, and pruritus.

For complete prescribing information for Atripla, visit www.atripla.com.

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.

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 as Truvada and Atripla are used over longer periods of time by many patients taking numerous other medicines, many of whom have underlying health problems, we may find new issues such as safety, resistance or drug interaction issues, which may require us to provide additional warnings or contraindications on our labels or narrow our approved indications, each of which could reduce the market acceptance of these products. 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 Annual Report on Form 10-K for the year ended December 31, 2006 and its Quarterly Reports on Form 10-Q for the first and second quarters of 2007, 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 statements.

U.S. full prescribing information for Truvada, Atripla, Viread and Emtriva are available at www.gilead.com.

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For more information on 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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