Gilead Sciences Submits New Drug Application to U.S. FDA for Once-Daily Single-Tablet Regimen of Truvada(R) and TMC278 for HIV

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- Product Would Be Second Complete Single-Tablet Antiretroviral Regimen -

FOSTER CITY, Calif., Nov 23, 2010 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing approval of the single-tablet regimen of Truvada(R) (emtricitabine and tenofovir disoproxil fumarate) and Tibotec Pharmaceuticals' investigational non-nucleoside reverse transcriptase inhibitor TMC278 (rilpivirine hydrochloride) for HIV-1 infection in adults. If approved, this would be the second product that contains a complete HIV treatment regimen in a single once-daily tablet.

"Combination antiretroviral therapy has dramatically advanced the field of HIV medicine, but the need remains for new single-tablet regimens that are effective, safe and well tolerated," said John C. Martin, PhD, Chairman and Chief Executive Officer, Gilead Sciences. "Gilead is committed to helping advance HIV treatment by pursuing both scientific research and innovative partnerships that will deliver more options to the healthcare community. We are pleased to work with Tibotec to bring this potentially important new therapy to people living with HIV."

On July 23, 2010, Tibotec submitted an NDA for U.S. marketing approval of TMC278 for once-daily use with other antiretroviral agents. That NDA is supported by 48-week data from two Phase III double-blind, randomized studies (ECHO and THRIVE) that evaluated the safety and efficacy of TMC278 in treatment-naive HIV-1 infected adults, the majority of whom received TMC278 in combination with Truvada. The Gilead NDA for Truvada/TMC278 is supported by a bioequivalence study conducted by Gilead demonstrating that the formulation of the single-tablet regimen achieved the same levels of medication in the blood as the component products dosed simultaneously as individual pills.

On September 3, 2010, the European marketing applications for TMC278 and for the Truvada/TMC278 single-tablet regimen were filed simultaneously by Tibotec and Gilead, respectively.

Gilead entered into a license and collaboration agreement with Tibotec for the development and commercialization of the single-tablet regimen in July 2009. Subject to regulatory approval, Gilead will assume the lead role in the manufacturing, registration, distribution and commercialization of the single-tablet regimen worldwide, excluding the developing world and Japan. Tibotec will be responsible for the commercialization of TMC278 as a stand-alone product and will hold rights to co-promote the single-tablet regimen in these territories. The companies are currently working on an agreement to make the combination product available in the developing world.

Truvada/TMC278 is an investigational product and its safety and efficacy have not yet been established.

Important Product Safety Information About Truvada

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

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 including Viread (tenofovir disoproxil fumarate), a component of Truvada.Truvada is not approved for the treatment of chronic hepatitis B virus (HBV) infection and its safety and efficacy has not been established in patients co-infected with HBV and HIV-1.Severe acute exacerbations of hepatitis B have been reported in patients co-infected with HIV-1 and HBV who have discontinued Truvada. 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 HBV and HIV-1 and discontinue Truvada. If appropriate, initiation of anti-hepatitis B treatment may be warranted.

It is important for patients to be aware that anti-HIV medicines including Truvadado not cure HIV infection or AIDS and do not

reduce the risk of transmitting HIV to others.

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. 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 including patients who have previously experienced renal events while receiving Hepsera(R) (adefovir dipivoxil).

Dosing interval adjustment and close monitoring of renal function are recommended in all patients with creatinine clearance 30-49 ml/min. Truvada should be avoided with concurrent or recent use of a nephrotoxic agent. Truvada should not be administered with Hepsera.

Truvada should not be coadministered with Emtriva, Viread, Atripla(R) (efavirenz 600 mg/emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) or lamivudine-containing products, including Combivir(R) (lamivudine/zidovudine), Epivir(R) or Epivir-HBV(R) (lamivudine), Epzicom(R) (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.

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. BMD monitoring should be considered in patients with a history of pathologic fractures or who are at risk for osteopenia. Cases of osteomalacia (associated with proximal renal tubulopathy and which may contribute to fractures) have been reported in association with the use of Viread.

Redistribution/accumulation of body fat has been observed in patients taking antiretroviral medicines. Immune Reconstitution Syndrome has been reported in patients treated with combination therapy, including Viread and Emtriva, and may necessitate further evaluation and treatment. Early virologic failure has been reported in HIV-infected patients on regimens containing only three nucleoside reverse transcriptase inhibitors. Patients on a therapy utilizing a triple nucleoside-only regimen should be carefully monitored and considered for treatment modification.

Coadministration 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. Dose reduction of didanosine should be considered, if warranted. 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 boosted with ritonavir 100 mg. Atazanavir without ritonavir should not be co-administered with Truvada.

The most common adverse reactions (incidence greater-than or equal to 10 percent) are diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams and rash.

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 that the product can be offered at a no-profit price in parts of the world where the HIV/AIDS epidemic has hit the hardest.

For complete prescribing information for Truvada, visit www.Truvada.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 risks related to Gilead's ability to successfully commercialize the single-tablet regimen of Truvada/TMC278. For example, the FDA, European Medicines Agency or other regulatory agencies may not approve TMC278 or the single-tablet regimen of Truvada/TMC278 for the treatment of HIV-1 infection in adults, and any marketing approval, if granted, may have significant limitations on its use. Further, Gilead and Tibotec may make a strategic decision to discontinue development of the combination product if, for example, the market for the product fails to materialize as expected. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, 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 is available at www.Truvada.com.

U.S. full prescribing information for Atripla is available at www.Atripla.com.

U.S. full prescribing information for Viread is available at www.Viread.com.

U.S. full prescribing information for Emtriva is available at www.GileadHIV.com.

U.S. full prescribing information for Hepsera is available at www.Hepsera.com.

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

Atripla is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC.

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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