



## **Bristol-Myers Squibb and Gilead Sciences Expand Their Alliance to Include Commercialization of ATRIPLA(R) (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) in Europe**

December 11, 2007

PRINCETON, N.J. & FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 11, 2007--Bristol-Myers Squibb Company (NYSE:BMJ) and Gilead Sciences, Inc. (Nasdaq:GILD) today announced an agreement to commercialize ATRIPLA(R) (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) in Europe for the treatment of virologically suppressed adults with HIV-1 infection, subject to the product's approval by the European Commission. If approved, ATRIPLA would represent the first and only once-daily single tablet regimen for HIV-1 infection in the European Union. The companies expect the European Commission to issue its decision by the end of the year.

Under this agreement, Bristol-Myers Squibb and Gilead share responsibility for commercializing ATRIPLA throughout the European Union and certain other European countries. Gilead will record revenues from future net sales of ATRIPLA in most of the European countries, while Bristol-Myers Squibb will record revenues in most of the European countries at percentages relative to the contribution represented by its individual product.

Bristol-Myers Squibb recently concluded an agreement with Merck & Co., Inc. under which Merck granted Bristol-Myers Squibb rights to co-commercialize ATRIPLA with Gilead in all of the European Union and certain other European countries. Previously, Merck had the exclusive right to market any product containing efavirenz (a component of ATRIPLA) in all European countries other than the United Kingdom, Germany, France, Italy, Spain and the Republic of Ireland.

Efavirenz is marketed by Bristol-Myers Squibb under the tradename SUSTIVA(R) in the United States, Canada and six major countries of the European Union. Efavirenz will continue to be commercialized by Merck & Co, Inc, through its affiliate Merck Sharp & Dohme (MSD) Limited under the tradename STOCRIN(R) in all other countries within the European Union and many countries outside of the United States. Emtricitabine and tenofovir disoproxil fumarate are commercialized by Gilead under the tradenames Emtriva(R) and Viread(R), respectively, and are commonly prescribed together as a once-daily, fixed-dose tablet, marketed under the tradename Truvada(R) for use as part of combination therapy.

ATRIPLA is currently sold in the United States and Canada through a joint venture between Bristol-Myers Squibb and Gilead. ATRIPLA was approved by the U.S. Food and Drug Administration (FDA) in July 2006 and by Health Canada in October 2007. Gilead and Merck previously announced a collaboration to distribute ATRIPLA in developing countries.

Important Product Safety Information (including Boxed WARNINGS) About ATRIPLA (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), Emtriva (emtricitabine), Viread (tenofovir disoproxil fumarate (DF)) and Truvada (emtricitabine/tenofovir DF) in the United States

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.

Emtriva, Viread, 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 or Emtriva, 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, Viread, Emtriva, SUSTIVA and ATRIPLA do not cure HIV infection or AIDS and do not reduce the risk of transmitting HIV to others.

### Additional Important Information About ATRIPLA in the United States

ATRIPLA(R) (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) 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.

Coadministration of ATRIPLA with astemizole, bepridil, cisapride, midazolam, pimozide, triazolam, ergot derivatives, or voriconazole is contraindicated. Concomitant use of ATRIPLA with St. John's wort (*Hypericum perforatum*) or St. John's wort-containing products is not recommended.

Since ATRIPLA contains efavirenz, emtricitabine, and tenofovir DF, ATRIPLA should not be coadministered with SUSTIVA(R) (efavirenz), Emtriva, Viread, or Truvada(R) (emtricitabine/tenofovir DF). Due to similarities between emtricitabine and lamivudine, ATRIPLA should not be coadministered with drugs containing lamivudine, including Combivir(R) (lamivudine/zidovudine), Epivir(R) or Epivir-HBV(R) (lamivudine), Epzicom(TM) (abacavir sulfate/lamivudine), or Trizivir(R) (abacavir sulfate/lamivudine/zidovudine).

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 receiving 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 Days 1-2 of therapy and generally resolve after the first 2-4 weeks of therapy; they were severe in 2.0% of patients, and 2.1% of patients discontinued therapy.

After 4 weeks of therapy, the prevalence of 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.

It is recommended that creatinine clearance (CrCl) be calculated in all patients prior to initiating therapy and as clinically appropriate during therapy with ATRIPLA(R) (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), and routine monitoring of CrCl and serum phosphorous be performed for patients at risk of renal impairment. ATRIPLA should not be given to patients with CrCl less than 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 DF. 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 breast-feed while taking ATRIPLA. Barrier contraception must always be used in combination with other methods of contraception (e.g., 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. ATRIPLA should be discontinued in patients developing severe rash associated with blistering, desquamation, mucosal involvement, or fever. Skin discoloration, associated with emtricitabine, may also occur.

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 DF. Cases of osteomalacia (associated with proximal renal tubulopathy) have been reported in association with the use of tenofovir DF.

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/accumulation of body fat has 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.

Saquinavir should not be used as the only protease inhibitor in combination with ATRIPLA.

Coadministration of ATRIPLA and atazanavir is not recommended due to concerns regarding decreased atazanavir concentrations. Atazanavir and lopinavir/ritonavir have been shown to increase tenofovir concentrations. Patients on atazanavir or 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 with didanosine should be undertaken with caution. Patients receiving this combination should be monitored closely for didanosine-associated adverse events. See U.S. Full Prescribing Information for complete list of drug-drug interactions.

In Study 934, the most frequently reported grades 2-4 adverse events through 48 weeks in patients receiving efavirenz + emtricitabine + tenofovir DF were dizziness (8%), nausea (8%), diarrhea (7%), fatigue (7%), headache (5%), rash (5%), sinusitis (4%), depression (4%), insomnia (4%), and abnormal dreams (4%).

The dose of ATRIPLA is one tablet (containing 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir DF) once daily taken orally on an empty stomach. Dosing at bedtime may improve the tolerability of nervous system symptoms. ATRIPLA is not recommended for use in patients less than 18 years of age.

For complete U.S. prescribing information, including Boxed WARNINGS, for ATRIPLA, visit [www.atripla.com](http://www.atripla.com). For complete prescribing information for SUSTIVA, visit [www.bms.com](http://www.bms.com). For complete U.S. prescribing information for Truvada, Viread and Emtriva, including Boxed WARNINGS, visit [www.gilead.com](http://www.gilead.com).

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global pharmaceutical and related healthcare products company. Visit Bristol-Myers Squibb on the World Wide Web at [www.bms.com](http://www.bms.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. Visit Gilead on the World Wide Web at [www.gilead.com](http://www.gilead.com).

Forward-Looking Statements

Bristol-Myers Squibb Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding product development. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that ATRIPLA will receive regulatory approval in the European Union or other geographies. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol-Myers Squibb's business, including those identified in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2006 and in our Quarterly Reports on Form 10-Q, particularly under "Item 1A. Risk Factors". Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Gilead Sciences 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 the European Commission will not formally approve ATRIPLA for marketing in the European Union prior to the end of the year or at all, and any marketing approval, if granted, may have significant limitations on its use. 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'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 three quarters of 2007, 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, including Boxed WARNINGS, for ATRIPLA is available at [www.atripla.com](http://www.atripla.com). Full U.S. prescribing information for SUSTIVA is available at [www.bms.com](http://www.bms.com). Full U.S. prescribing information for Truvada, Viread and Emtriva, including Boxed WARNINGS, are available at [www.gilead.com](http://www.gilead.com).

EU Summary of Product Characteristics for Truvada, Viread, Emtriva, SUSTIVA and STOCRIN are available at <http://www.emea.europa.eu/htms/human/epar/a.htm>.

ATRIPLA is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC. SUSTIVA is a registered trademark of Bristol-Myers Squibb Pharma Company. STOCRIN is a registered trademark of Merck & Co., Inc. Truvada, Viread and Emtriva are all registered trademarks of Gilead Sciences, Inc.

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