

## **Bristol-Myers Squibb, Gilead Sciences and Merck & Co., Inc. Announce Plans to Develop Fixed-Dose Combination of Three HIV Medicines**

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NEW YORK & FOSTER CITY, Calif. & WHITEHOUSE STATION, N.J.--(BUSINESS WIRE)--May 16, 2004--

Companies Support U.S. Department of Health and Human Services'

Call to Increase Treatment Options for HIV in Developing World

Bristol-Myers Squibb Company (NYSE:BMJ), Gilead Sciences, Inc. (Nasdaq:GILD) and Merck & Co., Inc. (NYSE:MRK) announced today that they are in discussions on the development of a once-daily, fixed-dose combination of three anti-HIV drugs and are also considering certain co-packaging options for the individual products. The three companies welcome today's comments by U.S. Secretary of Health and Human Services Tommy Thompson on the need for increased treatment options for people with HIV/AIDS in the developing world.

This collaboration -- a multi-company effort to create a fixed-dose product with three patented HIV/AIDS medicines -- would be the first partnership of its kind in the field of HIV. The parties agree on the importance of the task -- to support the need for simplified treatment regimens, particularly in resource-constrained settings.

Fixed-dose combinations contain multiple medicines co-formulated in a single tablet, potentially simplifying combination therapy for HIV treaters and patients. This potential three-drug, fixed-dose combination would include two Gilead drugs, Viread(R) (tenofovir disoproxil fumarate) and Emtriva(TM) (emtricitabine). In March, Gilead filed regulatory applications in the United States and Europe for approval of a single-tablet fixed-dose combination of these two drugs. The third drug in the proposed combination, efavirenz, is marketed in the United States, Canada and certain European countries by Bristol-Myers Squibb as Sustiva(R) (efavirenz) and elsewhere by Merck under the brand name Stocrin(R) (efavirenz).

The companies plan to seek regulatory review and approval of the three-drug fixed-dose combination. The companies also are exploring a co-packaged version that would include the three products as an interim step until a fixed-dose combination product could be made available.

"We are pleased to be part of this pioneering initiative with Gilead and Merck and commend the Administration for their efforts to help bring new and better ways to fight the global HIV/AIDS pandemic," said Peter R. Dolan, Chairman and Chief Executive Officer of Bristol-Myers Squibb. "Given the complexities of this disease, and the unique challenges in delivering care and treatment in resource limited settings, we recognize the need to work together and combine our expertise to find innovative solutions. At Bristol-Myers Squibb, HIV/AIDS continues to be a major area of focus for our research, and we are committed to making our medicines available at no-profit in those countries hardest hit by this epidemic. In addition, in Africa, we are working with local communities through our \$115 million Secure the Future(R) program to help strengthen their ability to fight this disease."

"While we have made progress in the fight against HIV with new therapies that offer significant advances, further efforts are needed to deliver the benefits of these advancements to those patients most in need," commented John C. Martin, PhD, President and Chief Executive Officer, Gilead Sciences. "Gilead has initiated a program to provide our antiretrovirals at no profit to developing world countries, and we have been evaluating options for partnerships that will allow us to expand these efforts. We're very pleased with the support we have received from the U.S. government, and we look forward to working with partners from industry, governments and NGOs to increase treatment and treatment options for those affected by HIV and AIDS."

"We welcome the Administration's support for the expedited development of new combinations of HIV medications for use in the President's Emergency Plan for AIDS Relief (PEPFAR) and look forward to working with the FDA on this critical issue," said Raymond V. Gilmartin, Chairman, President and Chief Executive Officer of Merck & Co., Inc. "Merck has worked closely for some time with representatives of the WHO, UNAIDS, the Global Fund and the Administration to explore ways to accelerate the development of fixed-dose combinations. We are delighted to be part of this new initiative. The proposed triple combination is expected to be an important new tool offering once-a-day treatment in the fight against the AIDS epidemic."

About Efavirenz

Efavirenz is available only by prescription and is used in combination with other medicines to treat people who are infected with HIV. Efavirenz does not cure HIV or help prevent passing HIV to others. Efavirenz should not be taken with Hismanal(R) (astemizole), Propulsid(R) (cisapride), Versed(R) (midazolam), Halcion(R) (triazolam), or ergot derivatives. Doctors should be informed about any medications or herbal products (particularly St. John's wort) that their patients are taking. Many patients have dizziness, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams. These feelings tend to go away after taking the medication for a few weeks. A small number of patients have reported severe depression, strange thoughts, or angry behavior. There have been a few reports of suicide but it is not known if efavirenz was the cause. Women should not become pregnant or breastfeed while taking

efavirenz. Rash is another common side effect. Rashes usually go away without any change in treatment. Rash may be a serious problem in some children. If a child develops a rash, their doctor should be contacted right away. Changes in body fat have been seen in some patients taking HIV medicines. The cause and long-term effects are not known at this time. Efavirenz should be taken on an empty stomach, preferably at bedtime. Taking efavirenz with food increases the amount of medicine in the body, which may increase the frequency of side effects. Taking efavirenz at bedtime may make some side effects less bothersome. United States Full Prescribing Information is available at [www.sustiva.com](http://www.sustiva.com).

#### About Emtriva

In the United States, Emtriva is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults. In the European Union, Emtriva is indicated in combination with other antiretroviral agents for the treatment of HIV in adults and children.

Assessment of adverse events, as described in the U.S. package insert, is based on pooled data from two Phase III studies in which 571 treatment-naive and 440 treatment-experienced patients received Emtriva (n=580) or a comparator drug (n=431) for 48 weeks. The most common adverse events that occurred in patients receiving Emtriva were headache, diarrhea, nausea and rash, which were generally of mild to moderate severity. Approximately one percent of patients discontinued participation in the clinical studies due to 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 (excess pigmentation) on the palms and/or soles, was generally mild and asymptomatic. The mechanism and clinical significance are unknown. 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. In patients co-infected with HIV and chronic hepatitis B, exacerbations of hepatitis B have been reported in patients after discontinuation of Emtriva.

#### About Viread

In the United States, Viread is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults. Assessment of adverse reactions, as described in the U.S. package insert, is based on one study of treatment-experienced patients and one study of treatment-naive patients. In Study 907, a total of 550 treatment-experienced patients received treatment with Viread 300 mg (n=368) or placebo (n=182) for 24 weeks followed by extended treatment with the drug. In Study 903, a total of 600 patients received treatment with Viread (n=299) or stavudine (n=301) in combination with lamivudine and efavirenz for 48 weeks. The most common adverse events in these patients were dizziness and mild to moderate gastrointestinal events, such as nausea, diarrhea, vomiting and flatulence.

In clinical practice, a number of adverse events, including renal impairment, nausea, rash and asthenia (weakness) have been reported. 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. 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. In patients co-infected with HIV and the hepatitis B virus, exacerbations of hepatitis B have been reported in patients after discontinuation of Viread. Decreases in bone mineral density (BMD) at the lumbar spine and hip have been seen with the use of Viread. The clinical significance of changes in BMD and biochemical markers is unknown and follow-up is continuing to assess long-term impact.

#### About Bristol-Myers Squibb

Bristol-Myers Squibb is a global pharmaceutical and related healthcare products company whose mission is to extend and enhance human life. For more than a decade, Bristol-Myers Squibb Company has been a global leader in the science of infectious diseases and has invested consistently in innovative research leading to the development of important treatments for people with HIV/AIDS. 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 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. Visit Gilead on the World Wide Web at [www.gilead.com](http://www.gilead.com).

#### About Merck

Merck & Co., Inc. is a global research-driven pharmaceutical products company. Merck discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health, directly and through its joint ventures.

Forward-Looking Statements

Bristol-Myers Squibb Forward-Looking Statement

This press release contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans and projections regarding the Company's financial position, results of operations, market position, product development and business strategy. These statements may be identified by the fact that they use words such as "anticipate," "estimates," "should," "expect," "guidance," "project," "intend," "plan," "believe" and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. 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. These factors include, among other things, market factors, pricing controls and pressures, (including changes in rules and practices) of managed care groups and institutional and governmental purchasers, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical rebates and reimbursement, competitive product development, changes to wholesaler inventory levels, governmental regulations and legislation, difficulties and delays in product development, manufacturing and sales, patent positions, litigation, and the impact and result of any litigation or governmental investigations related to the financial statement restatement process. There can be no guarantees with respect to pipeline products that future clinical studies will support the data described in this release, that the products will receive regulatory approvals, or that they will prove to be commercially successful. For further details and a discussion of these and other risks and uncertainties, see the Company's Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

#### Gilead Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements include statements regarding product development and product potential and the ability of the companies to reach agreement on the potential collaboration. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Gilead undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Gilead's business, particularly those mentioned in the cautionary statements in the company's Form 10-K for the year ended December 31, 2003, and in periodic reports on Form 10-Q and Form 8-K.

#### Merck Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements include statements regarding product development. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the cautionary statements in Item 1 of Merck's Form 10-K for the year ended Dec. 31, 2003, and in Merck's periodic reports on Form 10-Q and Form 8-K (if any), which Merck incorporates by reference.

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