Bristol-Myers Squibb and Gilead Sciences Announce Licensing Agreement for Development and Commercialization of New Fixed-Dose Combination Pill for People Living with HIV

October 26, 2011 8:32 AM ET

PRINCETON, N.J. & FOSTER CITY, Calif., Oct 26, 2011 (BUSINESS WIRE) --

Bristol-Myers Squibb Company (NYSE: BMY) and Gilead Sciences, Inc. (Nasdaq: GILD) today announced a licensing agreement for Bristol-Myers Squibb to develop and commercialize a fixed-dose combination containing Bristol-Myers Squibb's protease inhibitor REYATAZ(R) (atazanavir sulfate) and Gilead's cobicistat, a pharmacoenhancing or "boosting" agent that increases blood levels of certain HIV medicines to potentially allow for one pill once daily dosing. Gilead is currently studying atazanavir and cobicistat in Phase 2 and 3 studies in HIV-1 treatment-naïve patients.

REYATAZ is a prescription medicine used in combination with other medicines to treat people 6 years of age and older who are infected with the human immunodeficiency virus (HIV). REYATAZ should not be taken if patients are allergic to REYATAZ or to any of its ingredients.

Bristol-Myers Squibb will be responsible for the formulation, manufacturing, development, registration, distribution, and commercialization of the REYATAZ and cobicistat fixed-dose combination worldwide. Under the terms of the agreement, Bristol-Myers Squibb will pay Gilead an undisclosed royalty based on annual net sales of the product. Gilead retains sole rights for the manufacture, development and commercialization of cobicistat as a stand-alone product and for use in combination with other agents.

"This collaboration with Gilead builds on Bristol-Myers Squibb's longstanding commitment to develop medicines that have the potential to provide meaningful benefit to HIV patients, specifically aiming to enhance treatment options," said Elliott Sigal, M.D., Ph.D., Executive Vice President, Chief Scientific Officer & President, R&D, Bristol-Myers Squibb. "A REYATAZ and cobicistat fixed-dose combination has the potential not only to help simplify HIV therapy but also to address an unmet medical need in HIV for additional, innovative treatment options."

"Cobicistat provides us with the potential to co-formulate with a variety of commercially available HIV medicines that require boosting for optimal efficacy, such as the protease inhibitor atazanavir," said Norbert Bischofberger, Ph.D., Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "This agreement represents a shared commitment between Gilead and Bristol-Myers Squibb to develop multiple treatment options that can address individual patient needs."

Cobicistat is Gilead's proprietary potent mechanism-based inhibitor of cytochrome P450 3A (CYP3A), an enzyme that metabolizes drugs in the body. Cobicistat is an investigational product and has not yet been determined to be safe or efficacious in humans.

IMPORTANT INFORMATION About REYATAZ(R) (atazanavir sulfate)

INDICATION: REYATAZ(R) is a prescription medicine used in combination with other medicines to treat people 6 years of age and older who are infected with the human immunodeficiency virus (HIV). REYATAZ has been studied in a 48-week trial in patients who have taken anti-HIV medicines and a 96-week trial in patients who have never taken anti-HIV medicines.

REYATAZ does not cure HIV or lower your chance of passing HIV to others. People taking REYATAZ may still get opportunistic infections or other conditions that happen with HIV infection.

IMPORTANT SAFETY INFORMATION:

Do not take REYATAZ if you are allergic to REYATAZ or to any of its ingredients.

Do not take REYATAZ if you are taking the following medicines due to potential for serious, life-threatening side effects or death:

Versed(R) (midazolam) when taken by mouth,Halcion(R) (triazolam), ergot medicines (dihydroergotamine, ergonovine, ergotamine, and methylergonovine such as Cafergot(R), Migranal(R), D.H.E. 45(R), ergotrate maleate, Methergine(R), and others), Propulsid(R) (cisapride), or Orap(R) (pimozide).

Do not take REYATAZ (atazanavir sulfate)with the following medicines due to potential for serious side effects: Camptosar(R) (irinotecan), Crixivan(R) (indinavir), Mevacor(R) (lovastatin), Zocor(R) (simvastatin), Uroxatral(R) (alfuzosin), or Revatio(R) (sildenafil).

Do not take REYATAZ with the following medicines as they may lower the amount of REYATAZ in your blood, which may lead to increased HIV viral load and resistance to REYATAZ or other anti-HIV medicines: rifampin (also known as Rimactane(R), Rifadin(R), Rifater(R), or Rifamate(R)), St. John's wort (*Hypericum perforatum*)-containing products, or Viramune (R) (nevirapine).

Serevent Diskus(R) (salmeterol) and Advair(R) (salmeterol with fluticasone) are **not recommended with REYATAZ(R)**.

Do not take Vfend(R) (voriconazole) if you are taking REYATAZ and Norvir(R) (ritonavir).

The above lists of medicines are not complete. **Taking REYATAZ with some other medicines may require your therapy to be monitored more closely or may require a change in dose or dose schedule of REYATAZ or the other medicine.** Discuss with your healthcare provider all prescription and non-prescription medicines, vitamin and herbal supplements, or other health preparations you are taking or plan to take.

Tell your healthcare provider if you are pregnant or plan to become pregnant. REYATAZ (atazanavir sulfate) use during pregnancy has not been associated with an increase in birth defects. Pregnant women have experienced serious side effects when taking REYATAZ with other HIV medicines called nucleoside analogues. **After your baby is born,** tell your healthcare provider if your baby's skin or the white part of his/her eyes turns yellow. **You should not breast-feed** if you are HIV-positive.

Also tell your healthcare provider if you have end-stage kidney disease managed with hemodialysis or **severe liver dysfunction**.

Tell your healthcare provider right away if you have any side effects, symptoms, or conditions, including the following:

- **Mild rash** (redness and itching) without other symptoms sometimes occurs in patients taking REYATAZ, most often in the first few weeks after the medicine is started, and usually goes away within 2 weeks with no change in treatment.
- **Severe rash** may develop with other symptoms that could be serious and potentially cause death. **If you develop a rash with any of the following symptoms, stop using REYATAZ and call your healthcare provider right away:**
  - Shortness of breath
  - General ill-feeling or "flu-like" symptoms
  - Fever
  - Muscle or joint aches
  - Conjunctivitis (red or inflamed eyes, like "pink-eye")
  - Blisters
  - Mouth sores
  - Swelling of your face
- **Yellowing of the skin and/or eyes** may occur due to increases in bilirubin levels in the blood (bilirubin is made by the liver).
- **A change in the way your heart beats** may occur. You may feel dizzy or lightheaded. These could be symptoms of a heart problem.
- **Diabetes and high blood sugar** may occur in patients taking protease inhibitor medicines like REYATAZ (atazanavir sulfate). Some patients may need changes in their diabetes medicine.
- **If you have liver disease**,including hepatitis B or C, it may get worse when you take anti-HIV medicines like REYATAZ.
- **Kidney stones** have been reported in patients takingREYATAZ. Signs or symptoms ofkidney stones include pain in your side, blood in your urine, and pain when you urinate.
- **Some patients with hemophilia** have increased bleeding problems with protease inhibitor medicines like REYATAZ.

- **Changes in body fat** have been seen in some patients taking anti-HIV medicines. The cause and long-term effects are not known at this time.
- **Immune reconstitution syndrome** has been seen in some patients with advanced HIV infection (AIDS) and a history of opportunistic infection. Signs and symptoms of inflammation from previous infections may occur soon after starting anti-HIV treatment, including REYATAZ(R) (atazanavir sulfate).
- **Gallbladder disorders** (including gallstones and gallbladder inflammation) have been reported in patients taking REYATAZ.

Other common side effects of REYATAZ taken with other anti-HIV medicines include: nausea; headache; stomach pain; vomiting; diarrhea; depression; fever; dizziness; trouble sleeping; numbness, tingling, or burning of hands or feet; and muscle pain.

You should take **REYATAZ once daily with food** (a meal or snack). Swallow the capsules whole; **do not open the capsules**. **You should take REYATAZ and your other anti-HIV medicines exactly as instructed by your healthcare provider**.

Available REYATAZ. capsule strengths include 200 mg and 300 mg.

Please see accompanying Full Prescribing Information, or click here.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit http://www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

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 Asia Pacific. For more information, please visit www.gilead.com.

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 the research, development and commercialization of pharmaceutical products.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 the compound described in this release will move from early stage development into full product development, that clinical trials of this compound will support a regulatory filing, or that the compound will receive regulatory approval or become a commercially successful product. Nor is there any guarantee that the transaction described in this release will receive the necessary regulatory approvals to close.Forward-looking statements in the press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2010, its Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K.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 risks related to whether ongoing clinical trials for cobicistat will be successful and the ability to formulate cobicistat with other agents, including atazanavir sulfate.In addition, safety and efficacy data from additional clinical trials may not warrant further development of cobicistat or the fixed-dose combination product, regulatory authorities may not approve cobicistat as a stand-alone product or in any combination product, and marketing approval, if granted, may have significant limitations on its use.

As a result, cobicistat and the fixed-dose combination product may never be successfully commercialized.The parties may make a strategic decision to discontinue development of the fixed-dose combination product if, for example, Bristol-Myers Squibb is unable to successfully formulate the fixed-dose combination product or 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.These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, 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.

SOURCE: Bristol-Myers Squibb Company and Gilead Sciences, Inc.

Bristol-Myers Squibb Company
Media:
Cristi Barnett, 609-252-6028
cristi.barnett@bms.com
or
Investors:
John Elicker, 609-252-4611
john.elicker@bms.com
or
GileadSciences
Media:
Erin Rau, 650-522-5635
erin.rau@gilead.com
or
Investors:
Susan Hubbard, 650-522-5715
susan.hubbard@gilead.com