U.S. Food & Drug Administration Approved the use of REYATAZ(R) (atazanavir sulfate) Boosted with Ritonavir, in Combination Therapy, for Previously Untreated HIV-1 Infected Adult Patients

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PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) announced today that the U.S. Food & Drug Administration (FDA) approved the use of REYATAZ® (atazanavir sulfate) 300 mg once-daily boosted with ritonavir 100 mg as part of combination therapy in previously untreated (treatment-naive) HIV-1 infected patients. REYATAZ boosted with ritonavir (REYATAZ/r) taken once daily with food is recognized by the U.S. Department of Health and Human Services (DHHS) as a preferred component of combination HIV therapy for treatment-naive patients.

For treatment-naive patients who are unable to tolerate ritonavir, REYATAZ 400 mg (without ritonavir), taken once daily with food, is recommended.

This use of once-daily REYATAZ/r in HIV-1 infected treatment-naive adult patients is based on 48-week results from the CASTLE study, which demonstrated similar antiviral efficacy of REYATAZ/r to twice-daily lopinavir/ritonavir (lopinavir/r), each as part of HIV combination therapy, in treatment-naive HIV-1 infected adult patients.

Within the CASTLE study, the REYATAZ/r arm was associated with low increases from baseline in total cholesterol (13 percent), LDL cholesterol (14 percent), HDL cholesterol (29 percent), and triglycerides (15 percent). The lopinavir/r arm was associated with 25 percent increase in total cholesterol, 19 percent increase in LDL cholesterol, 37 percent increase in HDL cholesterol, and 52 percent increase in triglycerides. Two percent of patients in the REYATAZ® (atazanavir sulfate)/r arm and eight percent of patients in the lopinavir/r arm required lipid-lowering therapy in the study, compared to 1 percent in each arm at baseline.

Safety events in this study were consistent with prior experience. Grade 2-4 treatment-related adverse events that occurred in two percent or greater of patients in the CASTLE study included jaundice (4 percent and zero percent), nausea (4 percent and 8 percent), diarrhea (2 percent and 11 percent) and rash (3 percent and 2 percent) in the REYATAZ/r and lopinavir/r arms, respectively. Grade 3–4 increases in total bilirubin were seen in 34 percent of patients in the REYATAZ/r arm and in less than 1 percent of patients in the lopinavir/r arm.

“Bristol-Myers Squibb is committed to developing medicines that enhance the care of people living with HIV and AIDS,” said Elliott Sigal, M.D., Ph.D., Executive Vice President, Chief Scientific Officer and President, Research and Development, Bristol-Myers Squibb. “Boosted REYATAZ provides health care professionals a newly approved, once-daily dosing option as part of combination therapy for patients naive to HIV therapy.”

About the CASTLE Study

The CASTLE study is the first large-scale (n=883), open-label, randomized study designed to demonstrate the non-inferiority of REYATAZ/r to lopinavir/r in treatment-naive HIV-1 infected adult patients. Forty-eight week data from the study were presented earlier this year at the 15th Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, Mass., and previously announced in a press release on February 6, 2008. Data from the CASTLE study were also published in the August 23 issue of The Lancet.

Important Information About REYATAZ® (atazanavir sulfate) 200 mg, 300 mg Capsules

REYATAZ is a prescription medicine used in combination with other medicines to treat people who are infected with the human immunodeficiency virus (HIV). REYATAZ has been studied in 48-week trials in both patients who have taken or have never taken anti-HIV medicines.

REYATAZ does not cure HIV or help prevent passing HIV to others.

REYATAZ should not be taken by patients allergic to REYATAZ or to any of its ingredients.

REYATAZ should not be taken with the following medicines: rifampin, Camptosar® (irinotecan), Versed® (midazolam) when taken by mouth, Halcion® (triazolam), ergot medicines, Propulsid® (cispapride), St. John’s wort (Hypericum perforatum), Mevacor® (lovastatin), Zocor® (simvastatin), Orap® (pimozide), Crixivan® (indinavir), or Viramune® (nevirapine).

Patients taking REYATAZ should speak with their healthcare provider before taking the following...
medicines: hormonal contraceptives such as birth control pills or contraceptive patch, Viagra® (sildenafil), Levitra® (vardenafil), Cialis® (tadalafil), Vfend® (voriconazole), Aciphex® (rabeprazole), Nexium® (esomeprazole), Prevacid® (lansoprazole), Prilosec® (omeprazole), Protonix® (pantoprazole), Axid® (nizatidine), Pepcid AC® (famotidine), Tagamet® (cimetidine), or Zantac® (ranitidine), Advair® (fluticasone propionate and salmeterol inhalation powder), Flonase® or Flovent® (fluticasone propionate), or Sustiva® (efavirenz).

The above lists of medicines are not complete. The use of all prescription and non-prescription medicines, vitamins, herbal supplements, or other health preparations should be discussed with a healthcare provider.

Any side effects, symptoms, or conditions, including the following, should be reported to a healthcare provider right away:

-- **Mild rash** (redness and itching) without other symptoms sometimes occurs in patients taking REYATAZ(R) (atazanavir sulfate), most often in the first few weeks after the medicine is started, and usually goes away within two weeks with no change in treatment.

-- **Severe rash** has occurred in a small number of patients taking REYATAZ. This type of rash is associated with other symptoms which could be serious and potentially cause death. If rash develops with any of the following symptoms, the patient should stop using REYATAZ and call a 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 the 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 the heart beats** may occur and could be a symptom of a heart problem.

-- **Diabetes and high blood sugar** may occur in patients taking protease inhibitor medicines like REYATAZ(R) (atazanavir sulfate).

-- **In patients with liver disease**, including hepatitis B or C, the liver disease may get worse when taking anti-HIV medicines like REYATAZ.

-- **Kidney stones** have been reported in patients taking REYATAZ. Signs or symptoms of kidney stones include pain in the side, blood in the urine, and pain when urinating.

-- **End stage kidney disease** managed with hemodialysis.

-- **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.

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

REYATAZ should be taken once daily with food (a meal or snack). REYATAZ and other anti-HIV medicines should be taken exactly as instructed by healthcare providers.

Please see accompanying Full Prescribing Information, or visit [http://www.reyataz.com](http://www.reyataz.com) or [http://www.BMS.com](http://www.BMS.com).

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About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to extend and enhance human life. For more information visit [www.bms.com](http://www.bms.com).


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