CORRECTING and REPLACING CASTLE Data Showed Boosted REYATAZ(R) (atazanavir sulfate) and Lopinavir/r Achieved Similar Results for Undetectable Viral Load in Treatment-Naive HIV-1 Infected Patients, Regardless of Gender

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CASTLE gender subanalysis provides largest scale information to date about boosted protease inhibitor-based combination HIV therapy in treatment-naive women

MEXICO CITY--(BUSINESS WIRE)--Please replace the release with the following corrected version due to multiple revisions.

The corrected version reads:

CASTLE DATA SHOWED BOOSTED REYATAZ® (ATAZANAVIR SULFATE) AND LOPINAVIR/R ACHIEVED SIMILAR RESULTS FOR UNDETECTABLE VIRAL LOAD IN TREATMENT-NAIVE HIV-1 INFECTED PATIENTS, REGARDLESS OF GENDER

CASTLE gender subanalysis provides largest scale information to date about boosted protease inhibitor-based combination HIV therapy in treatment-naive women

Bristol-Myers Squibb Company (NYSE: BMY) today announced results from a pre-specified subanalysis of the CASTLE study, in which once-daily boosted REYATAZ® (atazanavir sulfate) (REYATAZ 300 mg taken with 100 mg of ritonavir, or REYATAZ/r) and twice-daily co-formulated lopinavir 400 mg and ritonavir 100 mg (lopinavir/r), each as part of HIV combination therapy, showed similar results for undetectable viral load at 48 weeks regardless of gender in treatment-naive HIV-1 infected adults. Women comprise half of all people living with HIV around the world, and in 2006, more than 25 percent of new HIV-1 infections in the U.S. were in women. Moreover, women have been shown to have differences in HIV viral load, drug-related side effects and drug pharmacokinetics compared to men, but there are few data to guide decision-making about choice of therapy and dosing by gender.

CASTLE is the first large-scale, open-label, randomized study designed to demonstrate the non-inferiority of REYATAZ/r to lopinavir/r in previously untreated HIV-1 infected adult patients. The CASTLE gender subanalysis was conducted to determine the effect of both study regimens on women and men. The CASTLE study enrolled 277 women and 606 men from 29 countries. Results from this gender subanalysis were presented for the first time at the 17th International AIDS Conference (IAC) today in Mexico City.

"It is very important for women to be involved in clinical research so we can better understand efficacy and tolerability of antiretroviral therapy in women," said Dawn Averitt Bridge, Founder and Chair of the Board, The Well Project. "This subanalysis of the CASTLE study has made a significant contribution to that understanding."

Overall in the CASTLE study, 78 percent of the 440 patients in the REYATAZ® (atazanavir sulfate)/r arm and 76 percent of the 443 patients in the lopinavir/r arm met the non-inferiority primary endpoint of achieving undetectable viral load (defined as HIV-1 RNA less than 50 copies/mL) at 48 weeks.

The gender subanalysis data showed that 76 percent of the 138 female patients in the REYATAZ/r arm and 73 percent of the 139 female patients in the lopinavir/r arm achieved undetectable viral load at 48 weeks. In male patients, 79 percent of the 302 patients in the REYATAZ/r arm and 78 percent of the 304 patients in the lopinavir/r arm achieved undetectable viral load. In female patients, the mean increase in CD4+ cell count from baseline at 48 weeks was 199 cells/mm³ in the REYATAZ/r arm and 221 cells/mm³ in the lopinavir/r arm. In male patients, the mean increase in CD4+ cell count from baseline at 48 weeks was 205 cells/mm³ in the REYATAZ/r arm and 219 cells/mm³ in the lopinavir/r arm.

In female patients, Grade 2-4 treatment-related adverse events were reported by 30 percent in the REYATAZ/r arm and 32 percent in the lopinavir/r arm. In male patients, Grade 2-4 treatment-related adverse events were reported by 24 percent in the REYATAZ/r arm and 28 percent in the lopinavir/r arm.
About the CASTLE Study

The international, multi-center, open-label, non-inferiority, 96-week CASTLE study randomized 883 treatment-naive patients infected with HIV-1, of which 31 percent (n=277) were women and 69 percent (n=606) were men. Four hundred and forty patients were randomized to receive REYATAZ 300 mg and ritonavir 100 mg once daily and 443 patients were randomized to receive co-formulated lopinavir 400 mg and ritonavir 100 mg twice daily, each in combination with a once-daily, fixed-dose combination of emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg. Patients were required to have a baseline viral load (HIV-1 RNA) of greater than or equal to 5,000 copies/mL; there was no CD4+ cell count restriction for study entry. The primary endpoint for the study was the proportion of patients who achieved undetectable viral load (HIV-1 RNA of less than 50 copies/mL) at 48 weeks.

Important Information About REYATAZ® (atazanavir sulfate) Capsules

REYATAZ® (atazanavir sulfate) is a protease inhibitor that has been studied extensively in both treatment-naive and treatment-experienced HIV-infected patients and is administered once-daily in all patient populations.

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 with the following medicines: ergot medicines, Versed® (midazolam), Halcion® (triazolam), Orap® (pimozide), Propulsid® (cisapride), Camptosar® (irinotecan), Crixivan® (indinavir), Mevacor® (lovastatin), Zocor® (simvastatin), rifampin, or St. John’s wort (Hypericum perforatum).

People taking REYATAZ should speak with their healthcare provider before taking the following medicines: 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® (fluticasone propionate), or Flovent® (fluticasone propionate). The above lists of medicines are not complete. The use of all prescriptions and non-prescription medicines, vitamins, herbal supplements, or other health preparations should be discussed with a healthcare provider.

The following side effects or conditions should be reported to a healthcare provider right away:

- **A change in the way the heart beats** may occur and could be a symptom of a heart problem.

- **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 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).

- **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.

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

- **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 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 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).

REYATAZ® is a registered trademark of Bristol-Myers Squibb Company. The other brands listed are registered trademarks of their respective owners and are not trademarks of Bristol-Myers Squibb Company.

**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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