CASTLE Study Showed Similar Efficacy Among Once-Daily REYATAZ® (atazanavir sulfate)/ritonavir and Twice-Daily lopinavir/ritonavir at 48 Weeks in Previously Untreated HIV-Infected Adult Patients

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Data also showed differences in gastrointestinal and lipid effects between REYATAZ/ritonavir and lopinavir/ritonavir among study population

PRINCETON, NJ—BUSINESS WIRE—Bristol-Myers Squibb Company (NYSE: BMY) today announced results from the CASTLE study, in which 300 mg of once-daily REYATAZ® (atazanavir sulfate) taken with 100 mg of ritonavir showed similar antiviral efficacy to twice-daily lopinavir-400 mg and ritonavir 100 mg (lopinavir/r) in previously untreated adult HIV-1 infected patients at 48 weeks, as part of HIV combination therapy. In this study, 78 percent of the 449 patients in the REYATAZ/r arm met the primary endpoint of achieving undetectable viral load (defined as HIV-1 RNA less than 50 copies/mL) at 48 weeks, compared with 76 percent of the 443 patients in the lopinavir/r arm.

CASTLE is the first large-scale, open-label, randomized study designed to demonstrate the non-inferiority of REYATAZ/r to lopinavir in previously untreated HIV-1 infected adult patients. Data from the CASTLE study were presented for the first time at the 15th Conference on Retroviruses and Opportunistic Infections (CROI) this week in Boston, Mass.

"The CASTLE study provides important additional data to inform the use of a once-daily regimen including REYATAZ and ritonavir in antiretroviral-naive HIV-infected patients," said Jean-Michel Molina, M.D., Hopital Saint Louis, Paris, France. "When choosing a treatment in previously untreated patients it is important to ensure antiviral activity as well as tolerability to optimise the management of HIV infection over the long term."

The most common grade 2-4 adverse events occurring in greater than or equal to three percent of patients in the once-daily arm included nausea (four percent and eight percent, respectively), headache (four percent and zero percent, respectively), and rash (three percent and two percent, respectively).

Changes in body fat have been seen in some patients taking antiretroviral 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.

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

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. United States Full Prescribing Information for REYATAZ is available at http://www.reyataz.com.

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About Bristol-Myers Squibb


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