European Commission Approves Labelling Update For REYATAZ® (atazanavir sulfate) in Pregnant Women Living With HIV

REYATAZ is the only boosted PI to include dosing and medical guidance in pregnancy and postpartum in the label

Paris (PRWEB UK) 25 November 2011 -- Bristol-Myers Squibb Company today announced that the European Commission approved a labelling update for REYATAZ(atazanavir sulfate) based on new data generated in pregnant women living with HIV. The updated label provides dosing and medical guidance for REYATAZ/ritonavir during pregnancy and immediately following birth. The data came from study AI424-182, which evaluated the pharmacokinetic parameters, efficacy and safety of REYATAZ/ritonavirin pregnant women living with HIV.

Worldwide, more than 3 million women living with HIV give birth every year. According to European AIDS Clinical Society (EACS) treatment guidelines, some antiretroviral (ARV) drugs may be prescribed during pregnancy to reduce the mother’s viral load, although their optimal dosage is mostly unknown. As pregnancy can reduce the serum levels of many ARVs, it is important to know the optimal dosage.

“This labelling update is important news for both physicians and women with HIV of child-bearing age in that it provides dosing and medical guidance for the use of REYATAZ/ritonavir during pregnancy and postpartum,” said Margaret Johnson, Clinical Director of HIV Services, Royal Free NHS Trust, London.

This label update is based on a multicentre, open-label, prospective, single-arm pharmacokinetic study (Study AI424-182®). The study evaluated 41 pregnant women living with HIV, between 12 to 32 weeks gestation (second and third trimester of gestation) with CD4 ≥ 200 cells/mm3. Study participants were treated with REYATAZ with ritonavir 300/100 mg (n=20) or 400/100 mg (n=21) once daily in combination with zidovudine/lamivudine 300/150 mg twice daily; those in their second trimester received REYATAZ/ritonavir 300/100 mg.

The primary objective of the study was to determine the dosing of REYATAZ/ritonavir to produce adequate drug exposure in pregnant women with HIV compared to historical data in adults living with HIV. The results showed that both doses of REYATAZ achieved minimum plasma concentrations (24 hours post-dose) during the third trimester of pregnancy, comparable to that observed historically in adults living with HIV.

Secondary outcomes of the study evaluated antiviral efficacy and safety in pregnant women and their infants. Among the 39 women who completed the trial, 38 achieved an HIV RNA <50 copies/mL at time of delivery. Among the 40 infants tested (one patient withdrew), all were negative for HIV-1 DNA at the time of delivery and/or during the first six months postpartum. At the end of the study, 30% (6/20) of the women on REYATAZ/ritonavir 300/100 mg and 62% (13/21) of the women on REYATAZ/ritonavir 400/100 mg experienced grades 3 to 4 hyperbilirubinemia. Three of 20 infants (15%) born to women treated with REYATAZ/ritonavir 300/100 mg and four of 20 infants (20%) born to women treated with REYATAZ/ritonavir 400/100 mg experienced grade 3-4 bilirubin. No evidence of severe hyperbilirubinemia (total bilirubin levels greater than 20 mg/dL) or acute or chronic bilirubin encephalopathy was observed among newborns in this study. No cases of lactic acidosis were observed.

A moderate amount of data in pregnant women (between 300-1,000 pregnant outcomes) indicates no
malformative toxicity of atazanavir. Animal studies do not indicate reproductive toxicity. However, because the studies in humans cannot fully rule out the possibility of harm, REYATAZ may be considered during pregnancy only if the potential benefit justifies the risk.1

Important Information about REYATAZ (atazanavir sulfate) for pregnant HIV positive women

During the second and third trimesters of pregnancy:
REYATAZ 300 mg with ritonavir 100 mg may not provide sufficient exposure to REYATAZ, especially when the activity of REYATAZ or the whole regimen may be compromised due to drug resistance. Since there are limited data available and due to inter-patient variability during pregnancy, Therapeutic Drug Monitoring (TDM) may be considered to ensure adequate exposure.

The risk of a further decrease in REYATAZ exposure is expected when REYATAZ is given with medicinal products known to reduce its exposure (e.g., tenofovir or H2-receptor antagonists).
- If tenofovir or an H2-receptor antagonist is needed, a dose increase to REYATAZ 400 mg with ritonavir 100 mg with TDM may be considered.
- It is not recommended to use REYATAZ with ritonavir for pregnant patients who are receiving both tenofovir and an H2-receptor antagonist.

During postpartum:
Following a possible decrease in REYATAZ exposure during the second and third trimester, REYATAZ exposures might increase during the first two months after delivery. Therefore, postpartum patients should be closely monitored for adverse reactions.
- During this time, postpartum patients should follow the same dose recommendation as for non-pregnant patients, including those for co-administration of medicinal products known to affect REYATAZ exposure.
It is not known whether REYATAZ administered to the mother during pregnancy will exacerbate physiological hyperbilirubinaemia and lead to kernicterus in neonates and infants. In the prepartum period, additional monitoring should be considered.

Breast-feeding
It is unknown whether atazanavir or atazanavir metabolites are excreted in human milk. Studies in rats have demonstrated that atazanavir is excreted in the milk. As a general rule, it is recommended that HIV infected women not breast feed their infants in order to avoid transmission of HIV.

About REYATAZ
Developed by Bristol-Myers Squibb, REYATAZ (atazanavir sulfate) is an antiviral drug used in combination with other medicines to treat individuals infected with the human immunodeficiency virus-1 (HIV-1).1 REYATAZ was the first once-daily protease inhibitor launched in Europe. , REYATAZ has proven efficacy, safety and tolerability in HIV treatment-naïve and experienced patients.2, REYATAZ is the only boosted PI with labelling that allows for co-administration with an oral contraceptive.

About Pregnancy and HIV
Globally, the number of women living with HIV is on the rise. , The prevalence of pregnant women living with HIV in Europe has increased significantly in recent years, with a high proportion of women diagnosed during antenatal testing. This rate is increasing due to the growing influx of people living with HIV immigrating to Europe. In developing countries, many more pregnant women are also living with HIV. For example, in parts of Africa, the prevalence is about 30%.8

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About Bristol-Myers Squibb Company
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.

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References
1. Reyataz SmPC.

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