

Mylan's Matrix Receives Tentative FDA Approval Under PEPFAR for Generic Version of Reyataz(R) Capsules HIV Treatment

PITTSBURGH, Oct 05, 2010 /PRNewswire via COMTEX News Network/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Matrix Laboratories Limited has received tentative approval from the U.S. Food and Drug Administration (FDA) under the President's Emergency Plan for AIDS Relief (PEPFAR) for its Abbreviated New Drug Application (ANDA) for Atazanavir Sulfate Capsules, 150 mg and 300 mg. This product will be eligible for purchase outside the U.S. in certain developing countries.

Mylan President Heather Bresch said: "This approval is yet another step in improving access to quality, affordable treatment for people living with HIV/AIDS in developing countries. Atazanavir has a distinct resistance profile compared with other protease inhibitors and is an important addition to the product portfolio being made available to patients in developing countries. With every new generic antiretroviral (ARV), patient care in these affected areas improves and becomes more affordable."

Atazanavir Sulfate Capsules are the generic version of Bristol Myers Squibb's Reyataz(R) Capsules. It is used in combination with other medications to control HIV infection and is included in the ARV class of drugs known as HIV protease inhibitors. Unlike currently available protease inhibitors, Atazanavir offers once-daily dosing, a distinctive resistance profile and may result in fewer metabolic complications. Until now, a generic version of this product has not been made widely available in developing countries.

The FDA's tentative approval under PEPFAR means that Matrix's product meets all of the agency's manufacturing quality, safety and efficacy standards.

Matrix's wide range of ARV products includes active pharmaceutical ingredients (API) and first- and second-line finished doses. The company's emphasis on producing affordable products has allowed it to drive down the average annual cost per patient of effective therapies. Approximately 30% of HIV/AIDS patients in developing countries depend on a Matrix ARV product.

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 140 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios supported by a robust product pipeline; operates one of the world's largest active pharmaceutical ingredient manufacturers; and runs a specialty business focused on respiratory, allergy and psychiatric therapies. For more information, please visit www.mylan.com.

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