Mylan Receives Tentative FDA Approval Through PEPFAR for First Heat-Stable, Fixed-Dose Combination of Atazanavir Sulfate and Ritonavir Tablets for HIV/AIDS

- Product also 'prequalified' by WHO as a second-line treatment option -

PITTSBURGH, Dec. 1, 2011 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Laboratories Limited (formerly Matrix Laboratories Limited) has received tentative approval from the U.S. Food and Drug Administration (FDA) through the President's Emergency Plan for AIDS Relief (PEPFAR) for its New Drug Application (NDA) for Atazanavir Sulfate and Ritonavir Tablets, 300 mg/100 mg.

This product is the first heat-stable, fixed-dose combination of Atazanavir Sulfate and Ritonavir, an antiretroviral (ARV) used to treat HIV/AIDS. It also has been "prequalified" by the World Health Organization (WHO) as a second-line treatment option and can be used in combination with other ARVs for the treatment of HIV/AIDS. It will be eligible for purchase outside the U.S. in certain developing countries; it also will be a significant addition to Mylan's ARV portfolio in India, which is expected to become available during the second quarter of 2012.

Mylan President Heather Bresch said: "The approval of this fixed dose product is a groundbreaking development for the treatment of second-line HIV/AIDS patients. For the first time, it makes available a generic antiretroviral (ARV) drug with Atazanavir Sulfate and Ritonavir in a fixed-dose combination tablet. This 'combo' helps to facilitate treatment compliance for HIV/AIDS patients by providing a convenient, once-a-day dosing option, while reducing the cost of treatment for patients. The approval is representative of Mylan's continued commitment to providing critical life-saving therapies to people living with HIV/AIDS around the world."

The FDA's tentative approval through PEPFAR signifies that Mylan's product meets all of the agency's manufacturing quality, safety and efficacy standards. Atazanavir and Ritonavir are the generic versions of Bristol-Myers Squibb's Reyataz® and Abbott Laboratories' Norvir®, respectively.

Mylan's wide range of ARV products includes active pharmaceutical ingredients and 39 first- and second-line finished doses, eight of which are pediatric products. The company's emphasis on producing affordable products has allowed it to drive down the average annual cost per patient of effective therapies. Approximately one-third of HIV/AIDS patients in developing countries depend on a Mylan ARV product.

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 150 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 about Mylan, please visit www.mylan.com. For more information about generic drugs, please visit www.ChoosingGenerics.com.

SOURCE Mylan Inc.