Mylan's Matrix Receives Tentative FDA Approval Under PEPFAR for Abacavir Sulfate Tablets, 60 mg

PITTSBURGH, Dec. 7, 2010 /PRNewswire-FirstCall/ -- 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 New Drug Application (NDA) for Abacavir Sulfate Tablets, 60 mg. The NDA is based on the reference listed drug Ziagen® by ViiV Healthcare. This innovative pediatric dosage in tablet form was developed by Matrix for use in treating children with HIV/AIDS. This product will be eligible for purchase outside the U.S. in certain developing countries.

Mylan President Heather Bresch said: "This approval is particularly important because it adds to the available treatment options for children who are living with HIV/AIDS in developing countries. The addition of Abacavir to Mylan and Matrix's HIV/AIDS antiretroviral (ARV) franchise is a critical next step in helping to extend and improve the quality of life of people living with HIV/AIDS and to continue to expand access to high quality, affordable ARVs."

Abacavir Sulfate Tablets are used in combination with other medications to control HIV infection and is included in the ARV class of drugs known as nucleoside reverse transcriptase inhibitors. The tablet is a preferred form because it provides ease, accuracy and convenience of dosing over the currently available oral solutions.

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 and 33 first- and second-line finished doses, seven 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 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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