Mylan's Matrix Receives FDA Approval Under PEPFAR for Zidovudine Tablets, 100 mg

PITTSBURGH, March 10, 2011 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Matrix Laboratories Limited has received final 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 Zidovudine Tablets, 100 mg. The NDA is based on the reference listed drug Retrovir® Tablets, by ViiV Healthcare. This pediatric antiretroviral (ARV), the first of its kind in water-dispersible tablet form, was developed by Matrix for use in treating children with HIV/AIDS and in prevention of mother-to-child HIV transmission. This product will be eligible for purchase outside the U.S. in certain developing countries.

Mylan President Heather Bresch said: "According to PEPFAR, prevention of mother-to-child transmission (PMTCT) of HIV is extraordinarily effective. Without PMTCT, 25 to 40% of babies of HIV-positive mothers will be born infected; with PMTCT, that number drops to below 5%. With the approval of Zidovudine Tablets we are not only able to help treat children with HIV/AIDS in developing countries, but we are also able to help prevent HIV transmission before a child is even born. The approval of Zidovudine Tablets is a critical next step in helping to achieve UNAIDS' goal to eliminate mother-to-child transmission by 2015. With every generic ARV we bring to market we expand access to high quality, affordable HIV/AIDS medication in developing countries."

Zidovudine Tablets are used in combination with other medications to control HIV infection and also are used for the prevention of mother-to-child HIV-1 transmission. The product is included in the ARV class of drugs known as nucleoside reverse transcriptase inhibitors. The FDA's approval under PEPFAR means that Matrix's product meets all of the agency's manufacturing quality, safety and efficacy standards. The water-dispersible tablet is unique because it can be dispersed in water for all patients, adults or children, who are unable to swallow tablets.

Matrix's wide range of ARV products includes active pharmaceutical ingredients and 35 first- and second-line finished doses, nine 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 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.

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