Mylan's Matrix Receives Tentative FDA Approval Through PEPFAR for Novel "Co-Packaged" Version of HIV/AIDS Treatment

PITTSBURGH, Sept. 20, 2011 /PRNewswire/ -- 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) through the President's Emergency Plan for AIDS Relief (PEPFAR) for its New Drug Application (NDA) for Lamivudine / Tenofovir Disoproxil Fumarate Tablets, 300 mg/300 mg, co-packaged with Nevirapine Tablets, 200 mg. The product will be eligible for purchase outside the U.S. in certain developing countries.

(Photo: http://photos.prnewswire.com/prnh/20110920/NE71136)

Mylan President Heather Bresch said: "The approval of Lamivudine / Tenofovir Disoproxil Fumarate Tablets co-packaged with Nevirapine Tablets is an important product developed by Matrix for the treatment of HIV/AIDS. For the first time, it makes available a co-pack option that can help patients with the carrying and storage of this critical first-line ARV cocktail. Co-packs are convenient and may help to facilitate patient compliance with what often can be part of a burdensome drug regimen for HIV/AIDS patients managing many prescriptions and therapies."

This product offering is the first generic ARV drug product in a co-pack form and can be used alone or in combination with other ARVs for the treatment of HIV/AIDS. The FDA's tentative approval through PEPFAR signifies that Matrix's product meets all of the agency's manufacturing quality, safety and efficacy standards.

Lamivudine, Tenofovir Disoproxil Fumarate and Nevirapine are the generic versions of GlaxoSmithKline's Epivir®, Gilead Sciences' Viread® and Boehringer Ingelheim's Viramune®, respectively. This particular co-pack of ARV products also is suitable for the treatment of pregnant women with HIV/AIDS in certain countries where Lamivudine, Tenofovir Disoproxil Fumarate and Nevirapine are approved for use during pregnancy. Nevirapine is preferred over other drugs in the same class, such as Efavirenz, for pregnant women with HIV/AIDS.

Matrix's wide range of ARV products includes active pharmaceutical ingredients and 36 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 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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