Mylan's Matrix Receives First and Only Tentative FDA Approval Under PEPFAR for Generic Version of Atripla(R) HIV Treatment

PITTSBURGH, Aug. 18 /PRNewswire-FirstCall/ -- Mylan Inc. (Nasdaq: MYL) today announced that Matrix Laboratories, an Indian company in which Mylan owns a controlling stake, 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 a fixed-dose combination (FDC) of Efavirenz, Emtricitabine, Tenofovir Disoproxil Fumarate Tablets, 600 mg/200 mg/300 mg. This is the first and only generic version of this product and will be eligible for purchase outside the U.S. in many developing countries.

Mylan President Heather Bresch said: "This critical approval only further strengthens Mylan and Matrix's efforts to expand access to life-saving, affordable AIDS treatments for people living with HIV/AIDS in developing countries. Matrix's generic fixed-dose combination will dramatically improve access to this more patient-friendly medication while reducing the cost of treatment. Our commitment to growing Matrix's ARV (antiretroviral) franchise goes hand-in-hand with our desire to raise the standard of care in developing countries to the levels available in countries like the U.S."

The Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate FDC is the generic version of Gilead Sciences' Atripla Tablets, which are indicated for the treatment of HIV-1 infection in adults. It combines three anti-AIDS medicines into a single daily dose for either first- or second-line treatment and is one of the best-selling AIDS products in developed countries, with approximately $1.6 billion in U.S. sales alone for the twelve months ending

June 30, according to IMS Health. Until now, a generic version of this product has not been available in any market. Cocktails combining numerous drugs into a once daily dose can dramatically reduce pill burden, an improvement which has been shown to enhance patient compliance with complex treatment regimens.

The FDA's tentative approval under PEPFAR means that Matrix's product meets all of the agency's manufacturing quality, safety and efficacy standards. Although existing patents or exclusivity prevent its marketing in the U.S., the product will be eligible for purchase outside the U.S. in many developing countries.

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 at least one Matrix ARV product.

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

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08/18/2009

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