Mylan's Matrix Receives Tentative FDA Approval Under PEPFAR for Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets

PITTSBURGH, Sept 16, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Mylan Inc. (Nasdaq: MYL) today announced that its privately held Indian 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 Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 600 mg/300 mg/300 mg.

Mylan's product represents the first-ever fixed-dose combination of Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate and now provides Matrix with numerous Tenofovir combination product opportunities. This new drug adds to the Matrix portfolio of important treatments for HIV/AIDS. The product may be used for either first- or second-line treatment in adults. People use second-line therapies if and when they develop resistance to initially prescribed treatments.

Mylan President Heather Bresch said: "This product represents yet another important advance in our continuing fight against the global epidemic of HIV/AIDS. By combining three antiretroviral (ARV) products into a once-daily dose, we can dramatically improve the quality of care for people living with HIV/AIDS in emerging markets. Lower pill burden also increases the likelihood that patients adhere to treatment. This innovation also adds another affordable option to our large and rapidly growing portfolio of life-sustaining ARV products."

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 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 who are receiving treatment depend on Matrix ARV products.

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 the world's third largest active pharmaceutical ingredient manufacturer; and runs a specialty business focused on respiratory and allergy therapies. For more information, please visit www.mylan.com.

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