Mylan Receives Tentative FDA Approval Under PEPFAR for Matrix Laboratories' New Drug Application (NDA) for Efavirenz Tablets

PITTSBURGH, Dec 22, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- 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 Efavirenz Tablets, 50 mg, 100 mg and 200 mg. These innovative pediatric dosages in tablet form were developed by Matrix for use in treating pediatric HIV/AIDS.

Mylan President Heather Bresch commented: "This New Drug Application represents another successful innovation by Matrix in the fight against HIV/AIDS. Our HIV/AIDS antiretroviral (ARV) franchise continues to grow and to bring more affordable, high quality medications to patients in the developing world. We are extremely pleased to be able to add these new dosages to the basket of treatment options currently available to the medical community, and to expand our portfolio of products for treating pediatric HIV/AIDS."

Efavirenz is a non-nucleoside reverse transcriptase inhibitor (nNRTI) that has been found to be effective in many combination regimens for the treatment of HIV infection, both in treatment-naive and in treatment-experienced individuals.

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 person of effective therapies. Approximately 30% of people living with HIV/AIDS 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 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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