Mylan's Matrix Receives Tentative FDA Approval Under PEPFAR for First Generic, Heat-Stable Version of HIV Protease Inhibitor

Provides first affordable protease inhibitor for patients in developing countries Complements recent WHO approval earned for the same product

PITTSBURGH, March 12 /PRNewswire-FirstCall/ -- Mylan Inc. (Nasdaq: MYL) today announced that Matrix Laboratories Limited, its India-based subsidiary in which it holds a 71.5% controlling interest, has received the first and only 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 Lopinavir/Ritonavir Tablets, 200 mg/50 mg. Matrix's version of this product is heat-stable and affordable, making it practical for distribution and use in warm climates.

Mylan Vice Chairman and CEO Robert J. Coury said: "Mylan and Matrix are committed to our growing and high quality antiretroviral franchise. Our goal is to provide HIV treatments to patients around the world -- especially in developing countries. With Matrix's heat-stable and affordable version of Lopinavir/Ritonavir, patients in remote parts of developing nations will have access to this important life-saving drug. This is the second regulatory approval that this important product has recently earned, which further confirms our commitment to providing high-quality medicines at affordable prices."

Lopinavir/Ritonavir Tablets are the generic version of Abbott Laboratories' Kaletra® Tablets, the brand marketed in the U.S. and Europe, and Aluvia® Tablets, the brand marketed in developing countries. It is used in combination with other medications to control HIV infection and is included in the antiretroviral (ARV) class of drugs known as HIV protease inhibitors.

Last month, Matrix was awarded the first and only World Health Organization (WHO) approval for the same product. These approvals indicate that Matrix's Lopinavir/Ritonavir tablets meet international safety, efficacy and manufacturing quality standards. This status will significantly increase access to affordable, high quality medicines in many countries, particularly priority countries with high AIDS prevalence rates.

Matrix's wide range of ARV products includes active pharmaceutical ingredients (API) and first- and second-line finished doses. Patients often use second-line therapies if and when they develop resistance to initially prescribed treatments or experience clinical failures. 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 Matrix ARV products.

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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