Mylan Announces Tentative FDA Approval Under PEPFAR for Tenofovir Disoproxil Fumarate Tablets

PITTSBURGH, Dec. 4 /PRNewswire-FirstCall/ -- Mylan Inc. (NYSE: MYL) today announced that 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 Abbreviated New Drug Application (ANDA) for Tenofovir Disoproxil Fumarate Tablets, 300 mg. Matrix's Tenofovir Disoproxil Fumarate is the first and only generic tentative approval of Gilead Sciences Inc.'s Viread Tablets, 300 mg.

Matrix's ANDA was tentatively approved in less than six months and is the seventh PEPFAR tentative approval earned by Matrix within the last 12 months. Under PEPFAR, a tentative approval means that a company can immediately sell an HIV/AIDS treatment in certain countries outside of the United States. Although existing patents and/or marketing exclusivity prevent the approval of the product in the United States, a tentative approval indicates that the product meets all safety, efficacy and manufacturing quality standards for marketing in the United States, which helps to ensure AIDS patients abroad who receive these medications get the same quality product as the American public.

Mylan Vice Chairman and CEO Robert J. Coury said: "This is yet another milestone for Mylan and Matrix and their commitment to the Company's growing antiretroviral (ARV) franchise that includes active pharmaceutical ingredients (API) and finished dosage forms for first- and second-line treatments. We applaud Matrix for its high quality science and manufacturing capabilities that resulted in earning this important tentative approval in such a short timeframe. Tenofovir Disoproxil Fumarate will help to meet the urgent and increasing need for high quality, affordable treatment in the developing world where the prevalence of HIV/AIDS is socially and economically devastating."

Mylan Inc. is one of the world's leading quality generic and specialty pharmaceutical companies. The Company offers one of the industry's broadest and highest quality product portfolios, a robust product pipeline and a global commercial footprint through operations in more than 90 countries. Through its controlling interest in Matrix Laboratories Limited, Mylan has direct access to one of the largest active pharmaceutical ingredient (API) manufacturers in the world. Dey L.P., Mylan's fully integrated specialty business, provides the Company with innovative and diversified opportunities in the respiratory and allergy therapeutic areas. For more information about Mylan, please visit www.mylan.com.

*Matrix is a publicly-owned company in India in which Mylan owns a 71.5% controlling interest and is the world's leading provider of API used to produce generic ARV drugs for the treatment of HIV/AIDS.

SOURCE Mylan Inc. 12/04/2007 CONTACT: Media: Steven Zylstra +1-724-514-1800or Investors: Kris King, +1-724-514-1800both of Mylan Inc. Web site: http://www.mylan.com (MYL)