



## **Mylan Receives Tentative FDA Approval Through PEPFAR for Pediatric HIV/AIDS Therapy**

PITTSBURGH, Feb. 23, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Laboratories Limited (formerly 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 Abacavir Sulfate and Lamivudine Tablets, 60 mg/30 mg. This fixed-dose combination (FDC) product was developed for use in treating children with HIV/AIDS and is based on the adult-strength, brand version of the product EPZICOM®, by Viiv Healthcare. Mylan received tentative PEPFAR approval for its adult-strength, generic version of EPZICOM on Mar. 30, 2009.

Mylan CEO Heather Bresch said: "The approval of Abacavir Sulfate and Lamivudine further supports Mylan's mission to continue expanding access to high quality medicine around the world, which is especially crucial for children living with HIV/AIDS. This product combines two medications in one tablet, which may support treatment adherence in children as it reduces the pill burden often associated with complex antiretroviral regimens."

Abacavir Sulfate and Lamivudine Tablets are used in combination with other medications to control HIV infection. The FDA's tentative approval under PEPFAR means that Mylan's product meets all of the agency's manufacturing quality, safety and efficacy standards. Mylan also has received approval for this pediatric FDC therapy from the World Health Organization (WHO) under their Prequalification of Medicines Programme. The product will be eligible for purchase outside the U.S. in certain developing countries.

Mylan's wide range of ARV products includes active pharmaceutical ingredients and 42 first- and second-line finished doses, nine of which are pediatric products. The company's emphasis on producing affordable products has allowed it to drive down the average annual cost per patient of effective therapies. Approximately one-third of HIV/AIDS patients in developing countries depend on a Mylan ARV product.

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 150 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 about Mylan, please visit [www.mylan.com](http://www.mylan.com). For more information about generic drugs, please visit [www.ChoosingGenerics.com](http://www.ChoosingGenerics.com).

SOURCE Mylan Inc.

News Provided by Acquire Media