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Mylan Launches Generic Viramune XR®

PITTSBURGH, Oct. 30, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced the U.S. launch of its Nevirapine Extended-release tablets, 400 mg, which is the generic version of Boehringer Ingelheim's Viramune XR®. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is indicated for combination antiretroviral (ARV) treatment of HIV-1 infection in adults and in children six to less than 18 years of age(1). The launch of this product continues to strengthen Mylan's growing ARV portfolio in the U.S. Mylan has begun shipping product.

Nevirapine Extended-release tablets, 400 mg had U.S. sales of approximately $61.9 million for the 12 months ending September 30, 2014, according to IMS Health.

Currently, Mylan has 287 ANDAs pending FDA approval representing $112.2 billion in annual brand sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing $29.3 billion in annual brand sales, for the 12 months ending June 30, 2014, according to IMS Health.

Mylan is a global pharmaceutical company committed to setting new standards in health care. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. Learn more at mylan.com.

(1) Severe, life-threatening, and in some cases fatal liver toxicity and skin reactions have been reported with the use of Nevirapine Extended-release tablets. Monitoring by your healthcare provider is essential during the first 18 weeks of therapy.

SOURCE Mylan Inc.