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Mylan Launches Generic Myfortic® Delayed-Release Tablets

- Company awarded 180 days marketing exclusivity on the 360 mg strength -

PITTSBURGH, Jan. 9, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its U.S.-based subsidiary Mylan Pharmaceuticals Inc. has launched Mycophenolic Acid Delayed-release Tablets, 180 mg and 360 mg. This product is the generic version of Novartis' Myfortic® Delayed-release Tablets. Mylan was the first company to have filed a substantially complete Abbreviated New Drug Application (ANDA) containing a Paragraph IV patent certification for Mycophenolic Acid Delayed-release Tablets, 360 mg, and was awarded 180 days of marketing exclusivity for this strength. The company received final approval from the U.S. Food and Drug Administration (FDA) for its ANDA for this product.

Mycophenolic Acid Delayed-release Tablets, 180 mg and 360 mg, had U.S. sales of approximately \$306.8 million for the 12 months ending Sept. 30, 2013, according to IMS Health. Mycophenolic Acid Delayed-release Tablets are indicated for the prophylaxis of organ rejection in adult patients receiving a kidney transplant and for the prophylaxis of organ rejection in pediatric patients 5 years of age and older who are at least 6 months post kidney transplant.(1)

Currently, Mylan has 187 ANDAs pending FDA approval representing \$93.7 billion in annual sales, according to IMS Health. Forty of these pending ANDAs are potential first-to-file opportunities, representing \$24 billion in annual brand sales, for the 12 months ending June 30, 2013, according to IMS Health. When including ANDAs associated with Mylan's recent acquisition of Agila, the company now has a total of 287 ANDAs pending FDA approval.

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. But don't take our word for it. See for yourself. See inside. mylan.com

(1) Use during pregnancy is associated with increased risk of birth defects. Women of child bearing age must be counseled regarding pregnancy prevention. Use of mycophenolic acid delayed release tablets is associated with suppression of the immune system and can increase the risk of lymphoma and other malignancies, particularly of the skin. There is also an increased risk of bacterial, viral, fungal, and protozoal infections.

SOURCE Mylan Inc.

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