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Mylan Launches Generic Avapro® Tablets and Generic Avalide® Tablets

PITTSBURGH, Sept. 28, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals Inc. has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Irbesartan Tablets USP, 75 mg, 150 mg and 300 mg, the generic version of Sanofi's Avapro®. The company also received final approval from the FDA for its ANDA for Irbesartan and Hydrochlorothiazide Tablets USP, 150/12.5mg and 300/12.5 mg, the generic version of Sanofi's Avalide®. Irbesartan Tablets are indicated for the treatment of hypertension and in patients with type 2 diabetic nephropathy, and Irbesartan and Hydrochlorothiazide Tablets are indicated for hypertension in patients not adequately controlled with a single drug, and as initial therapy in patients likely to need multiple drugs to achieve blood pressure control.(1)

Irbesartan Tablets USP, 75 mg, 150 mg and 300 mg, had U.S. sales of approximately $400.7 million for the 12 months ending June 30, 2012, and Irbesartan and Hydrochlorothiazide Tablets USP, 150/12.5mg and 300/12.5 mg, had U.S. sales of approximately $117.4 million, according to IMS Health. Mylan is shipping both products immediately.

Currently, Mylan has 168 ANDAs pending FDA approval representing $79 billion in annual sales, according to IMS Health. Thirty-three of these pending ANDAs are potential first-to-file opportunities, representing $20.7 billion in annual brand sales, for the 12 months ending June 30, 2012, 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 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 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately one-third 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 150 countries and territories. Our workforce of more than 18,000 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) Irbesartan and Irbesartan and Hydrochlorothiazide Tablets can cause injury and death to the developing fetus and therefore should be discontinued if pregnancy occurs. They should also not be used in people who are allergic to any component of the product or to other sulfonamide-derived drugs. Other precautions for both products include: excessive reductions in blood pressure, decreased renal function, and potassium and electrolyte abnormalities. Reports of exacerbation or activation of systemic lupus erythematosus, drug interactions with lithium, visual changes and metabolic disturbances and impaired liver function have been associated with Irbesartan and Hydrochlorothiazide Tablets. If any of these conditions occur or are suspected, medical attention should be sought.

SOURCE Mylan Inc.

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