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Mylan Launches Generic Exforge® Tablets

POTTERS BAR, England and PITTSBURGH, March 31, 2015 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced the U.S. launch of Amlodipine and Valsartan Tablets, 5 mg/160 mg, 5 mg/320 mg, 10 mg/160 mg, 10 mg/320 mg, which is the generic version of Novartis' Exforge® Tablets. 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 the treatment of hypertension, to lower blood pressure in patients not adequately controlled with monotherapy or as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.(1)

Amlodipine and Valsartan Tablets, 5 mg/160 mg, 5 mg/320 mg, 10 mg/160 mg, 10 mg/320 mg had U.S. sales of approximately \$415.3 million for the 12 months ending December 31, 2014, according to IMS Health.

Currently, Mylan has 269 ANDAs pending FDA approval representing \$104.1 billion in annual brand sales, according to IMS Health. Forty-four of these pending ANDAs are potential first-to-file opportunities, representing \$27.3 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 healthcare. 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 around 1,400 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 about 145 countries and territories. Our workforce of approximately 30,000 people is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

(1) Drugs that act directly on the renin-angiotensin system can cause injury and death to a developing fetus. Amlodipine and Valsartan should be discontinued when pregnancy is first detected.

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