

November 5, 2014

Mylan Launches Generic Loestrin 24 Fe®

PITTSBURGH, Nov. 5, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced the U.S. launch of its Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg and Ferrous Fumarate, which is the generic version of Warner Chilcott's Loestrin 24 Fe[®]. 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 prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.(1) Mylan has begun shipping product.

Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg and Ferrous Fumarate had U.S. sales of approximately \$24.4 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) Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use and this risk increases with age. Women who use oral contraceptives should be advised to not smoke. Consult your physician prior to beginning oral contraceptive use.

SOURCE Mylan Inc.

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