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Mylan Launches First Generic Version of Generess Fe®

-180 days of marketing exclusivity awarded -

POTTERS BAR, ENGLAND, and PITTSBURGH, April 7, 2015 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced the U.S. launch of Norethindrone and Ethinyl Estradiol Tablets (Chewable) 0.8 mg/0.025 mg and Ferrous Fumarate Tablets, 75 mg (Chewable), which is the generic version of Warner Chilcott's Generess® Fe Tablets. Mylan's partner Famy Care Ltd. 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's immediate shipment of Norethindrone and Ethinyl Estradiol Tablets (Chewable) 0.8 mg/0.025 mg and Ferrous Fumarate Tablets, 75 mg (Chewable) represents the company's ninth oral contraceptive product launch in the U.S.

Norethindrone and Ethinyl Estradiol Tablets (Chewable) 0.8 mg/0.025 mg and Ferrous Fumarate Tablets, 75 mg (Chewable) had U.S. sales of approximately \$114.7 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) 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.

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/mylan-launches-first-generic-version-of-generess-fe-300061502.html>

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