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Mylan Launches Generic Nordette® 28 Tablets

PITTSBURGH, Dec. 28, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its partner Famy Care Ltd. has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg. This product is the generic version of Teva Branded Pharmaceutical Products' Nordette® 28 Tablets, which are indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception.(1) The product will be distributed in the U.S. by Mylan Pharmaceuticals Inc., and the company is shipping product immediately.

Mylan CEO Heather Bresch commented: "The approval and immediate launch of our Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg, represents an exciting advance for the women's health care franchise that Mylan is establishing in partnership with Famy Care Ltd., one of the world's largest manufacturers of oral contraceptives. Presently, we have 34 oral contraceptives pending approval with the FDA and expect to receive additional approvals of these products beginning in next year's first quarter."

Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg, had U.S. sales of approximately \$60.4 million for the 12 months ending Sept. 30, 2012, according to IMS Health.

Currently, Mylan has 185 ANDAs pending FDA approval representing \$80.6 billion in annual sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing \$21.2 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) 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.

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