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Mylan Launches Generic Ortho Tri-Cyclen Lo® Tablets

HERTFORDSHIRE, England and PITTSBURGH, Jan. 5, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.025 mg, 0.215 mg/0.025 mg, and 0.25 mg/0.025 mg, which is the generic version of Janssen's Ortho Tri-Cyclen Lo® 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 prevention of pregnancy.(1)

Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.025 mg, 0.215 mg/0.025 mg, and 0.25 mg/0.025 mg, had U.S. sales of approximately \$488.6 million for the 12 months ending Sept. 30, 2015, according to IMS Health. This product represents Mylan's 14th oral contraceptive launch in the U.S.

Currently, Mylan has 270 ANDAs pending FDA approval representing \$101.5 billion in annual brand sales, according to IMS Health. Fifty of these pending ANDAs are potential first-to-file opportunities, representing \$35.6 billion in annual brand sales, for the 12 months ending June 30, 2015, 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 more than 1,400 generic and branded pharmaceuticals, including antiretroviral therapies on which nearly 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in approximately 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 30,000-strong workforce 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.

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