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Mylan Launches Generic Zovia® Tablets

HERTFORDSHIRE, England and PITTSBURGH, Dec. 28, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL), today announced the U.S. launch of Ethynodiol Diacetate and Ethinyl Estradiol Tablets USP, 1 mg / 0.05 mg. Mylan's product was determined to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Zovia® 1/50E-28 Tablets (Watson). Mylan's subsidiary, Jai Pharma Limited, 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 use by women to prevent pregnancy. (1)



Currently, Mylan has more than 240 ANDAs pending FDA approval representing approximately \$95.6 billion in annual brand sales, according to IMS Health. Forty-one of these pending ANDAs are potential first-to-file opportunities, representing \$32.5 billion in annual brand sales, for the 12 months ending June 30, 2016, 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 2,700 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS worldwide depend. We market our products in more than 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 35,000-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 adverse effects on the heart and blood vessels from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives are strongly advised not to smoke.

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