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Mylan Launches First Generic Version of Vivelle-DOT®

PITTSBURGH, Dec. 22, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced the U.S. launch of its Estradiol Transdermal System USP, 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day (Twice Weekly), which is the generic version of Novartis' Vivelle-DOT®. 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 treatment of moderate to severe vasomotor symptoms and moderate to severe symptoms of vulvar and vaginal atrophy due to menopause; hypoestrogenism due to hypogonadism, castration or primary ovarian failure; and the prevention of postmenopausal osteoporosis.(1)

Mylan CEO Heather Bresch commented: "The approval of Mylan's Estradiol Transdermal System USP represents our seventh U.S. transdermal product launch and strengthens the company's growing portfolio of women's health products. We look forward to continuing to meet patient needs in this space as we strive to provide the world's 7 billion people access to high quality medicines."

Estradiol Transdermal System USP, 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day (Twice Weekly), had U.S. sales of approximately \$262.5 million for the 12 months ending September 30, 2014, according to IMS Health.

Currently, Mylan has 285 ANDAs pending FDA approval representing \$111.3 billion in annual brand sales, according to IMS Health. Forty-four 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 25,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. Learn more at mylan.com.

This press release includes statements that constitute "forward-looking statements," including with regard to the company's strategy, future growth and performance. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: the impacts of competition; changes in economic and financial conditions of the company's business; strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; uncertainties and matters beyond the control of management; and the other risks detailed in the company's filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

(1) There is an increased risk of endometrial cancer, stroke and deep vein thrombosis in a woman who uses unopposed estrogens. Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia. The Women's Health Initiative (WHI) reported an increased risk of developing dementia in postmenopausal women 65 years of age or older, as well as, an increased risk of invasive breast cancer and myocardial infarction if taking Estrogen plus progestin.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/mylan-launches-first-generic-version-of-vivelle-dot-300012970.html>

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