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Mylan Adds to U.S. Women's Healthcare Portfolio With FDA Approval of First Generic for Estrace® Cream

Mylan now offers estradiol in four delivery methods The approval showcases Mylan's ongoing investment in complex products

HERTFORDSHIRE, England and PITTSBURGH, Dec. 29, 2017 /PRNewswire/ -- Global pharmaceutical leader [Mylan](#) N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Estradiol Vaginal Cream USP, 0.01%, the first generic version of Allergan's Estrace® Cream. 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 in the treatment of vulvar and vaginal atrophy.

Mylan CEO [Heather Bresch](#) said, "The approval and launch of Estradiol Vaginal Cream strengthens our robust [women's healthcare portfolio](#) and our commitment to helping women manage their health across every stage of their lives, from contraception and hormone replacement therapy to certain disorders that are highly prevalent in women, like hypothyroidism. Mylan is now one of only a few companies that will offer Estradiol as an option across four delivery systems - cream, gel, transdermal patch and tablet. This breadth allows us to deliver multiple options and, ultimately, greater value to customers, healthcare professionals and patients. Further, introducing a first-time generic demonstrates our leadership in continuing to create access to high quality medicine for patients and the U.S. healthcare system."

Mylan President [Rajiv Malik](#) added, "Topicals like Estradiol Vaginal Cream are a great example of Mylan's ability to bring to market complex products. We have made substantial investments in research and development of these difficult-to-develop medicines and believe this provides long-term sustainability for our business."

Estrogens increase the risk of endometrial cancer, and should not be used for the prevention of cardiovascular disease or dementia. Estrogen use is associated with an increased risk of stroke, DVT and dementia in postmenopausal women. Because of the risks associated with estrogen use, they should be prescribed at the lowest effective dose and for the shortest duration.

Estradiol Vaginal Cream USP, 0.01%, had U.S. sales of approximately \$449 million for the 12 months ending Oct. 31, 2017, according to IQVIA.

Currently, Mylan has 211 ANDAs pending FDA approval representing approximately \$93.4 billion in annual brand sales, according to IQVIA. Forty-six of these pending ANDAs are potential first-to-file opportunities, representing \$42.1 billion in annual brand sales, for the 12 months ending July 31, 2017, according to IQVIA.

This press release includes statements that constitute "forward-looking statements," including with regard to: the approval and launch of Estradiol Vaginal Cream strengthening Mylan's robust women's healthcare portfolio and our commitment to helping women manage their health across every stage of their lives; Mylan now being one of only a few companies that will offer Estradiol as an option across four delivery systems - cream, gel, transdermal patch and tablet; topicals like Estradiol Vaginal Cream being a great example of Mylan's ability to not only produce complex products, but to bring them to market first; this breadth allowing Mylan to deliver multiple options and, ultimately, greater value to customers, healthcare professionals and patients; introducing a first-time generic demonstrating Mylan's leadership in continuing to create access to high quality medicine for patients and the U.S. healthcare system; and Mylan making substantial investments in research and development of these difficult-to-develop medicines and believing this provides long-term sustainability for our business. 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: any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the

businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

About Mylan

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 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. 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. We routinely post information that may be important to investors on our website at investor.mylan.com.



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