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Mylan Launches First Generic Doryx® Delayed-Release Tablets, 200 mg

- Company awarded 180 days marketing exclusivity -

HERTFORDSHIRE, England and PITTSBURGH, May 23, 2016 /PRNewswire/ -- Mylan N.V. (Nasdaq: MYL, TASE: MYL) today announced the U.S. launch of Doxycycline Hyclate Delayed-Release (DR) Tablets USP, 200 mg, a generic version of Mayne's Doryx®. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its supplemental Abbreviated New Drug Application (sANDA) and was awarded 180 days of marketing exclusivity for this product. Doxycycline Hyclate DR Tablets are a tetracycline-class antimicrobial indicated as adjunctive therapy for severe acne.

Doxycycline Hyclate DR Tablets USP, 200 mg, had U.S. sales of approximately \$181.8 million for the 12 months ending March 31, 2016, according to IMS Health.

Currently, Mylan has 258 ANDAs pending FDA approval representing \$109 billion in annual brand sales, according to IMS Health. Forty-five of these pending ANDAs are potential first-to-file opportunities, representing \$37.4 billion in annual brand sales, for the 12 months ending December 31, 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 approximately 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 nearly 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at <u>mylan.com</u>.

To view the original version on PR Newswire, visit:<u>http://www.prnewswire.com/news-releases/mylan-launches-first-generic-doryx-delayed-release-tablets-200-mg-300272372.html</u>

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