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Mylan Launches Generic Avodart® Capsules

HERTFORDSHIRE, England and PITTSBURGH, June 24, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Dutasteride Capsules, 0.5 mg, the generic version of GlaxoSmithKline's Avodart® Capsules. 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 as monotherapy for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention and reduce the risk of the need for BPH-related surgery. It may also be used with tamsulosin for the treatment of symptomatic BPH in men with an enlarged prostate.



Dutasteride Capsules, 0.5 mg, had U.S. sales of approximately \$297.2 million for the 12 months ending April 30, 2016, according to IMS Health.

Currently, Mylan has 248 ANDAs pending FDA approval representing \$107.6 billion in annual brand sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing \$37.2 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 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.

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