

September 18, 2015

Mylan Launches One of First Generic Lescol XL® Tablets

HERTFORDSHIRE, England and PITTSBURGH, Sept. 18, 2015 /PRNewswire/ -- Mylan N.V. (Nasdaq: MYL) today announced the U.S. launch of Fluvastatin Sodium Extended-release Tablets, 80 mg, which is the generic version of Novartis' Lescol XL[®] Tablets. 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 to reduce elevated total cholesterol, LDL-C, Apo B, and triglyceride, and increase HDL-C in adults with primary hypercholesterolaemia and mixed dyslipidaemia, as an adjunct to diet, when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate.

Fluvastatin Sodium Extended-release Tablets, 80 mg, had U.S. sales of approximately \$37.6 million for the 12 months ending June 30, 2015, according to IMS Health.

Currently, Mylan has 262 ANDAs pending FDA approval representing \$99.3 billion in annual brand sales, according to IMS Health. Fifty of these pending ANDAs are potential first-to-file opportunities, representing \$33.4 billion in annual brand sales, for the 12 months ending December 31, 2014, 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 around 1,400 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which nearly 50% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in about 145 countries and territories. Our workforce of approximately 30,000 people is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

To view the original version on PR Newswire, visit:<u>http://www.prnewswire.com/news-releases/mylan-launches-one-of-first-generic-lescol-xl-tablets-300145468.html</u>

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