



October 27, 2015

Mylan Launches Generic Fusilev® for Injection

HERTFORDSHIRE, England and PITTSBURGH, Oct. 27, 2015 /PRNewswire/ -- Mylan N.V. (Nasdaq: MYL) today announced the U.S. launch of Levoleucovorin Calcium Injection 10 mg (base)/mL; 175 mg (base)/17.5 mL and 250 mg (base)/25 mL Single-use Vials, which is the generic version of Spectrum Pharmaceuticals' Fusilev® for Injection. 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 rescue use after high-dose methotrexate therapy in osteosarcoma. Levoleucovorin is also indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists.

Levoleucovorin Calcium Injection 10 mg (base)/mL; 175 mg (base)/17.5 mL and 250 mg (base)/25 mL Single-use Vials had U.S. sales of approximately \$200 million for the 12 months ending June 30, 2015, according to IMS Health.

Currently, Mylan has 259 ANDAs pending FDA approval representing \$98.5 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: <http://www.prnewswire.com/news-releases/mylan-launches-generic-fusilev-for-injection-300166836.html>

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