June 2, 2015

Mylan Launches Generic INTUNIV® Tablets

HERTFORDSHIRE, England, and PITTSBURGH, June 2, 2015 /PRNewswire/ -- Mylan N.V. (Nasdaq: MYL) today announced the U.S. launch of Guanfacine Extended-release Tablets, 1 mg, 2 mg, 3 mg, and 4 mg, which is the generic version of Shire's INTUNIV® 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 for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications.

Guanfacine Extended-release Tablets, 1 mg, 2 mg, 3 mg, and 4 mg, had U.S. sales of approximately $804.9 million for the 12 months ending March 31, 2015, according to IMS Health.

Currently, Mylan has 271 ANDAs pending FDA approval representing $106 billion in annual brand sales, according to IMS Health. Forty-seven of these pending ANDAs are potential first-to-file opportunities, representing $32 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 approximately 40% 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-intuniv-tablets-300092876.html

SOURCE Mylan N.V.