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Mylan Launches First Generic Focalin XR® Capsules, 30 mg

- Company awarded 180 days marketing exclusivity -

PITTSBURGH, Nov. 18, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals Inc. has launched Dexmethylphenidate Hydrochloride Extended-release (ER) Capsules, 30 mg, which is the first generic version of Novartis' Focalin XR®. Mylan was the first company to have filed a substantially complete Abbreviated New Drug Application (ANDA) containing a Paragraph IV patent certification for Dexmethylphenidate Hydrochloride ER Capsules, 30 mg. The company received final approval from the U.S. Food and Drug Administration (FDA) for its ANDA for this product and was awarded 180 days of marketing exclusivity.

According to IMS Health, Dexmethylphenidate Hydrochloride ER Capsules, 30 mg, had U.S. sales of approximately \$67.34 million for the 12 months ending Sept. 30, 2013. This product is a central nervous system stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients age 6 years and older.

Currently, Mylan has 179 ANDAs pending FDA approval representing \$90.5 billion in annual sales, according to IMS Health. Forty of these pending ANDAs are potential first-to-file opportunities, representing \$24.1 billion in annual brand sales, for the 12 months ending June 30, 2013, according to IMS Health.

Mylan is a global pharmaceutical company committed to setting new standards in health care. 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 1,200 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 approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. mylan.com

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