



August 1, 2016

Mylan Launches Generic Dexedrine® Capsules

HERTFORDSHIRE, England and PITTSBURGH, Aug. 1, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Dextroamphetamine Sulfate Extended-release Capsules, 5 mg, 10 mg, and 15 mg, a generic version of Amedra Pharmaceuticals LLC's Dexedrine®. 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 in narcolepsy and attention deficit disorder with hyperactivity as an integral part of a total treatment program that typically includes other measures (psychological, educational, social) for patients (ages 6 years to 16 years) with this syndrome.(1)



Dextroamphetamine Sulfate Extended-release Capsules, 5 mg, 10 mg, and 15 mg, had U.S. sales of approximately \$101.3 million for the 12 months ending May 31, 2016, according to IMS Health.

Currently, Mylan has 245 ANDAs pending FDA approval representing \$101.6 billion in annual brand sales, according to IMS Health. Forty-one of these pending ANDAs are potential first-to-file opportunities, representing \$30.8 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.

(1) Amphetamines have a high potential for abuse. Administration of amphetamines for prolonged periods of time may lead to drug dependency and must be avoided. Particular attention should be paid to the possibility of subjects obtaining amphetamines for non-therapeutic use or distribution to others, and the drugs should be prescribed or dispensed sparingly. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events.

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