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Mylan Launches Generic Concerta® Tablets

HERTFORDSHIRE, England and PITTSBURGH, Dec. 29, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL), today announced the U.S. launch of Methylphenidate Hydrochloride Extended-Release Tablets USP, 18 mg, 27 mg, 36 mg and 54 mg, a generic version of Janssen's Concerta® 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). (1)



Mylan CEO Heather Bresch commented, "The launch of generic Concerta® Tablets demonstrates Mylan's leadership in complex development and manufacturing and in bringing to market a broad portfolio of high quality generics. This launch also further strengthens our robust portfolio of central nervous system medications, which is the largest in the U.S. with more than 100 products. We're excited about bringing another generic in this therapeutic area to market and expanding access to help patients."

Methylphenidate Hydrochloride Extended-Release Tablets USP, 18 mg, 27 mg, 36 mg and 54 mg, had U.S. sales of approximately \$1.59 billion for the 12 months ending October 31, 2016, according to IMS Health.

Currently, Mylan has more than 240 ANDAs pending FDA approval representing approximately \$95.6 billion in annual brand sales, according to IMS Health. Forty-one of these pending ANDAs are potential first-to-file opportunities, representing \$32.5 billion in annual brand sales, for the 12 months ending June 30, 2016, 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 2,700 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS worldwide depend. We market our products in more than 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) Methylphenidate HCl ER Tablets USP, 18 mg, 27 mg, 36 mg and 54 mg should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior.

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