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Mylan announces U.S. launch of generic Concerta Tablets

Dec 30 2016

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."

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.

Source:

Mylan N.V.
