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Mylan Launches Generic Invega® Tablets

HERTFORDSHIRE, England and PITTSBURGH, Sept. 28, 2015 /PRNewswire/ -- Mylan N.V. (Nasdaq: MYL) today announced the U.S. launch of Paliperidone Extended-Release Tablets 1.5 mg, 3 mg, 6 mg and 9 mg, the generic version of Janssen's Invega®. 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 schizophrenia in adults and adolescents (12 - 17 years of age) in addition to schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants in adults. (1)

Paliperidone Extended-Release Tablets 1.5 mg, 3 mg, 6 mg and 9 mg, had U.S. sales of approximately \$606.2 million for the 12 months ending June 30, 2015, according to IMS Health.

Currently, Mylan has 260 ANDAs pending FDA approval representing \$98.7 billion in annual brand sales, according to IMS Health. Fifty of these pending ANDAs are potential first-to-file opportunities, representing \$33.4 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 nearly 50% 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.

(1) Paliperidone Extended-Release Tablets is an atypical antipsychotic and is not approved for the treatment of patients with dementia-related psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

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