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Mylan Launches Generic FazaClo® Orally Disintegrating Tablets

HERTFORDSHIRE, England and PITTSBURGH, Nov. 24, 2015 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Clozapine Orally Disintegrating Tablets, 25 mg and 100 mg, the generic version of Jazz Pharmaceutical's FazaClo®. 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 used for the treatment of severely ill patients with schizophrenia who fail to respond adequately to standard antipsychotic treatment.(1)

Clozapine Orally Disintegrating Tablets, 25 mg and 100 mg, had U.S. sales of approximately \$51.1 million for the 12 months ending Sept. 30, 2015, according to IMS Health.

Currently, Mylan has 272 ANDAs pending FDA approval representing \$101.8 billion in annual brand sales, according to IMS Health. Fifty of these pending ANDAs are potential first-to-file opportunities, representing \$36.1 billion in annual brand sales, for the 12 months ending June 30, 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 nearly 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 30,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

(1) Clozapine Orally Disintegrating Tablets can cause severe neutropenia, orthostatic hypotension, bradycardia, and syncope, seizures, myocarditis and cardiomyopathy and has been shown to increase mortality in elderly patients with dementia-related psychosis. Any questions should be directed to the treating physician.

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