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Mylan Launches Generic Felbatol® Tablets

HERTFORDSHIRE, England and PITTSBURGH, Jan. 19, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Felbamate Tablets USP, 400 mg and 600 mg, which is the generic version of Meda Pharms' Felbatol® Tablets. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product. Felbamate Tablets are recommended for monotherapy or adjunctive therapy in the treatment of partial seizures, with and without generalization, in adults with epilepsy and as adjunctive therapy in the treatment of partial and generalized seizures associated with Lennox-Gastaut syndrome in children.(1) Â

Felbamate Tablets USP, 400 mg and 600 mg, had U.S. sales of approximately \$53 million for the 12 months ending Nov. 30, 2015, according to IMS Health.

Currently, Mylan has 269 ANDAs pending FDA approval representing \$101.5 billion in annual brand sales, according to IMS Health. Fifty of these pending ANDAs are potential first-to-file opportunities, representing \$35.6 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) Felbamate should only be used in patients who respond inadequately to alternative treatments and whose epilepsy is so severe that the benefits of treatment with Felbamate outweighs the risk of aplastic anemia and/or liver failure. Felbamate should not be used in patients with a history of any blood dyscrasias or hepatic dysfunction. Antiepileptic drugs including Felbamate, have been observed to increase the risk of suicidal thoughts and behaviors. Patients should consult their physician with any questions or concerns before taking Felbamate.

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