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Mylan Confirms Approval of sANDA for Bupropion Hydrochloride Extended-Release Tablets USP (XL), 300 mg

-Company continues to supply product to U.S. market -

PITTSBURGH, Aug. 22, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that the company has received approval from the U.S. Food and Drug Administration (FDA) for its supplemental Abbreviated New Drug Application (sANDA) providing bioequivalence study results requested by FDA for Bupropion Hydrochloride (HCl) Extended-release (ER) Tablets USP (XL), 300 mg. Bupropion HCl ER Tablets USP (XL) are the generic version of WELLBUTRIN XL® and are indicated for the treatment of major depressive disorder (MDD).(1) Mylan launched its Bupropion HCl ER Tablets USP (XL), 150 mg and 300 mg, to the U.S. market in September 2010.

In a correspondence issued December 2012, FDA requested all generic drug companies marketing a version of Bupropion HCl ER Tablets, 300 mg, to conduct a fasting bioequivalence (BE) study comparing their Bupropion HCl ER tablets, 300 mg, to GSK's WELLBUTRIN XL (Bupropion Hydrochloride Extended-release) Tablets, 300 mg. In April 2013, Mylan submitted to FDA a sANDA containing the requested study, which demonstrated bioequivalence of Mylan's Bupropion HCl ER Tablets USP (XL), 300 mg, to WELLBUTRIN XL(R) Tablets, 300 mg.

For the 12 months ending June 30, 2013, Bupropion Hydrochloride Extended-release Tablets, 150 mg and 300 mg, had U.S. sales of approximately $503.3 million, according to IMS Health.

Currently, Mylan has 179 ANDAs pending FDA approval representing $84 billion in annual sales, according to IMS Health. Forty-two of these pending ANDAs are potential first-to-file opportunities, representing $23.8 billion in annual brand sales, for the 12 months ending Dec. 31, 2012, according to IMS Health.

Mylan is a global pharmaceutical company committed to setting new standards in health care. 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 approximately 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. mylan.com

(1) Patients with a seizure disorder and pediatric patients should not take Bupropion. Antidepressant medications have been shown to increase the risk of suicide, compared to placebo, in children, adolescents and young adults. Bupropion HCl ER Tablets USP (XL) should not be used for smoking cessation.

SOURCE Mylan Inc.