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Mylan Launches Generic Subutex® Sublingual Tablets

POTTERS BAR, England and PITTSBURGH, March 11, 2015 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) and Mylan Inc. today announced the U.S. launch of Buprenorphine Hydrochloride Sublingual Tablets, 2 mg and 8 mg, which is the generic version of Reckitt Benckiser's Subutex® Sublingual 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 opioid dependence and is preferred for induction.

Buprenorphine Hydrochloride Sublingual Tablets, 2mg and 8mg had U.S. sales of approximately \$107.8 million for the 12 months ending December 31, 2014, according to IMS Health.

Currently, Mylan has 281 ANDAs pending FDA approval representing \$104.6 billion in annual brand sales, according to IMS Health. Forty-four of these pending ANDAs are potential first-to-file opportunities, representing \$27.3 billion in annual brand sales, for the 12 months ending June 30, 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 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 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.

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