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Mar 11, 2015

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# Mylan Launches Generic Subutex® Sublingual Tablets

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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](http://mylan.com).

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/mylan-launches-generic-subutex-sublingual-tablets-300048812.html>

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## Mylan Launches Generic Antabuse® Tablets

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POTTERS BAR, England and PITTSBURGH, March 11, 2015 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) and Mylan Inc. today announced the U.S. launch of Disulfiram Tablets USP, 250 mg and 500 mg, which is the generic version of Odyssey Pharmaceutical's Antabuse®. 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 an aid in the management of selected chronic alcohol patients who want to remain in a state of enforced sobriety so that supportive and psychotherapeutic treatment may be applied to the best advantage.(1)

Disulfiram Tablets USP, 250 mg and 500 mg, had U.S. sales of approximately \$16.4 million for the 12 months ending December 31, 2014, according to IMS Health.

Currently, Mylan has 282 ANDAs pending FDA approval representing \$104.7 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.

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(1) Disulfiram should never be administered to a patient when he is in a state of alcohol intoxication, or without his full knowledge. Disulfiram plus alcohol, even small amounts, produce flushing, throbbing in head and neck, throbbing headache, respiratory difficulty, nausea, copious vomiting, sweating, thirst, chest pain, palpitation, dyspnea, hyperventilation, tachycardia, hypotension, syncope, marked uneasiness, weakness, vertigo, blurred vision, and confusion. In severe reactions there may be respiratory depression, cardiovascular collapse, arrhythmias, myocardial infarction, acute congestive heart failure, unconsciousness, convulsions, and death.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/mylan-launches-generic-antabuse-tablets-300048810.html>

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SOURCE Mylan N.V.

For further information: Nina Devlin (Media), 724.514.1968; Kris King (Investors), 724.514.1813

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# Mylan Launches First and Only Available Intermediate Dosage Strengths of Fentanyl Transdermal System 37.5, 62.5 and 87.5 mcg/hr

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POTTERS BAR, England and PITTSBURGH, March 11, 2015 /[PRNewswire](#)/ -- Mylan N.V. (Nasdaq: MYL) and Mylan Inc. today announced the U.S. launch of its Fentanyl Transdermal System 37.5, 62.5 and 87.5 mcg/hr, adding to its existing offering of Fentanyl Transdermal System 12, 25, 50, 75 and 100 mcg/hr. Mylan currently is the only manufacturer that offers eight Fentanyl Transdermal System dosage strengths, including three new strengths – the first and only available "intermediate" dosages.

Mylan CEO Heather Bresch commented: "Mylan's launch of Fentanyl Transdermal System 37.5, 62.5 and 87.5 mcg/hr, is an example of our commitment to innovate to satisfy unmet needs. Mylan's Fentanyl Transdermal System is the number one dispensed fentanyl transdermal system in the U.S., and now, for the first time, patients have access to additional dosing options through Mylan's launch of three new strengths."

Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Supplemental Abbreviated New Drug Application (ANDA) for its Fentanyl Transdermal System 37.5, 62.5 and 87.5 mcg/hr.

Fentanyl Transdermal System's existing strengths, including the 12, 25, 50, 75 and 100 mcg/hr presentations, had U.S. sales of approximately \$767 million for the 12 months ending September 30, 2014, according to IMS Health.

Currently, Mylan has 282 ANDAs pending FDA approval representing \$104.6 billion in annual brand sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing \$27.2 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

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