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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

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.ⁱ, 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 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.

ⁱ IMS Health, NPA™, Dispensed Moving Annual Total (MAT) Prescription December 2013 through November 2014.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/mylan-launches-first-and-only-available-intermediate-dosage-strengths-of-fentanyl-transdermal-system-375-625-and-875-mcghr-300048809.html>

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