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Mylan Launches Generic Ultram® Extended-Release Tablets

HERTFORDSHIRE, England and PITTSBURGH, March 28, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Tramadol Hydrochloride Extended-release Tablets USP, 100 mg, 200 mg and 300 mg, which is the generic version of Valeant's Ultram® Extended-release 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 management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time.

Tramadol Hydrochloride Extended-release Tablets USP, 100 mg, 200 mg and 300 mg, had U.S. sales of approximately \$52.8 million for the 12 months ending Dec. 31, 2015, according to IMS Health.

Currently, Mylan has 265 ANDAs pending FDA approval representing \$110.3 billion in annual brand sales, according to IMS Health. Forty-eight of these pending ANDAs are potential first-to-file opportunities, representing \$38.3 billion in annual brand sales, for the 12 months ending Dec. 31, 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 nearly 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

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