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Mylan Launches Generic Dilantin® Chewable Tablets

PITTSBURGH, Dec. 28, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals Inc. has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Phenytoin Chewable Tablets USP, 50 mg. This product is the generic version of Pfizer's Dilantin® Chewable Tablets, which are indicated for the control of generalized tonic-clonic (grand mal) and complex partial (psychomotor, temporal lobe) seizures and prevention and treatment of seizures occurring during or following neurosurgery. Phenytoin serum level determinations may be necessary for optimal dosage adjustments

Phenytoin Chewable Tablets USP, 50 mg, had U.S. sales of approximately \$16.5 million for the 12 months ending Sept. 30, 2012, according to IMS Health. Mylan is shipping this product immediately.

Currently, Mylan has 185 ANDAs pending FDA approval representing \$80.6 billion in annual sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing \$21.2 billion in annual brand sales, for the 12 months ending June 30, 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 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 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately one-third 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 150 countries and territories. Our workforce of more than 18,000 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

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