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Mylan Launches Generic Version of Lithobid® Tablets

PITTSBURGH, July 3, 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 Lithium Carbonate Extended-release Tablets USP, 300 mg. This product is the generic version of Noven Therapeutic's Lithobid® Tablets, which are indicated for the treatment of manic episodes of bipolar disorder and as a maintenance treatment for individuals with a diagnosis of bipolar disorder.(1)

Lithium Carbonate Extended-release Tablets USP, 300 mg, had U.S. sales of approximately $21 million for the 12 months ending March 31, 2012, according to IMS Health. Mylan is shipping this product immediately.

Currently, Mylan has 167 ANDAs pending FDA approval representing $83.8 billion in annual sales, according to IMS Health. Thirty-seven of these pending ANDAs are potential first-to-file opportunities, representing $25.6 billion in annual brand sales, for the 12 months ending Dec. 31, 2011, 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

(1) Lithium toxicity is a serious condition and can occur at doses close to therapeutic concentrations. Patients should discontinue lithium therapy and contact their physician if signs of toxicity such as diarrhea, vomiting, tremor, unsteadiness, drowsiness or muscular weakness occur. There is also the potential to unmask a potentially fatal heart disorder called Brugada Syndrome. Patients should seek immediate emergency assistance if they experience fainting, lightheadedness, abnormal heart beats or shortness of breath. Consult your healthcare provider for further information about this product, including additional risk information.

SOURCE Mylan Inc.