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Mylan Launches Generic Version of Singulair® Tablets and Singulair® Chewable Tablets

PITTSBURGH, Aug. 7, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Montelukast Sodium Tablets, 10 mg, the generic version of Merck's Singulair® Tablets. Mylan also received final FDA approval for its ANDA for Montelukast Sodium Chewable Tablets, 4 mg and 5 mg, the generic version of Merck's Singulair® Chewable Tablets. These products are indicated for the prophylaxis and chronic treatment of asthma in patients two years of age and older, for prevention of exercise-induced bronchoconstriction in patients 15 years of age and older, and for the relief of symptoms of seasonal and perennial allergic rhinitis in patients two years of age and older.

Montelukast Sodium Tablets, 10 mg, had U.S. sales of approximately \$3.7 billion for the 12 months ending June 30, 2012, and Montelukast Sodium Chewable Tablets, 4 mg and 5 mg, had U.S. sales of approximately \$1.2 billion for the 12 months ending June 30, 2012, according to IMS Health. Mylan has begun shipping both of these products.

Currently, Mylan has 166 ANDAs pending FDA approval representing \$78.4 billion in annual sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing \$25.1 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

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