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Mylan Launches Generic Version of Plavix® Tablets

-Company Will Have 180 Days of Marketing Exclusivity for the 300 mg Strength-

PITTSBURGH, May 17, 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 Clopidogrel Tablets USP, 75 mg and 300 mg. The company was the first to have filed a substantially complete ANDA containing a Paragraph IV certification to the FDA for Clopidogrel Tablets, 300 mg, and was awarded 180 days of marketing exclusivity for this strength. This product is the generic version of Sanofi-Aventis' Plavix® and is indicated for acute coronary syndrome and for patients with a recent history of myocardial infarction, stroke or established peripheral arterial disease.[1]

Mylan Pharmaceuticals will provide customers with the 75 mg strength of this product in bottle form, and Mylan Institutional, which serves the institutional pharmaceutical market, will supply the 300 mg strength exclusively in unit dose packs of 30. This business also will supply Clopidogrel Tablets, 75 mg, in unit dose packs of 100. Mylan is shipping all product presentations immediately.

Plavix Tablets, 75 mg and 300 mg, had U.S. sales of approximately \$6.7 billion for the 12 months ending March 31, 2012, according to IMS Health.

Currently, Mylan has 173 ANDAs pending FDA approval representing \$98.2 billion in annual sales, according to IMS Health. Thirty-nine of these pending ANDAs are potential first-to-file opportunities, representing \$25.5 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] Clopidogrel has been shown to be less effective in people who are known as "CYP2C19 poor metabolizers." A blood test is used to determine if a person is a poor metabolizer. Clopidogrel is not indicated in those who are allergic to it or have active bleeding. Clopidogrel can increase the risk of bleeding and should be discontinued five days before surgery. Premature discontinuations can increase the risk for cardiovascular events and in patients who have had a recent transient ischemic attack or stroke. The combination of clopidogrel and aspirin can increase major bleeding. Fatal thrombotic thrombocytopenic purpura has also been reported.

SOURCE Mylan Inc.

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