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Mylan Launches Generic Version of Sporanox® Capsules

PITTSBURGH, July 27, 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 Itraconazole Capsules, 100 mg. This product is the generic version of Janssen Pharmaceutical Inc.'s Sporanox® and is indicated for the treatment of fungal infections that begin in the lungs, blatzomycosis, histoplasmosis, and aspergillosis in patients who are intolerant of or who are refractory to amphotericin B therapy. Itraconazole capsules are also indicated for the treatment of fungal infections of the toenails and fingernails in non-immunocompromised patients(1).

Itraconazole Capsules, 100 mg, had U.S. sales of approximately \$60 million for the 12 months ending March 31, 2012, according to IMS Health. Mylan is shipping this product immediately.

Currently, Mylan has 166 ANDAs pending FDA approval representing \$82.6 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

(1) Itraconazole can cause congestive heart failure and should not be given to people with a history of congestive heart failure and should be discontinued if signs or symptoms of congestive heart failure occur. Severe drug interactions, cardiac events and even death could occur if Itraconazole is coadministered with drugs that utilize the same metabolic pathway in the liver, therefore it is important to consult with your doctor before taking Itraconazole and make them aware of all prescribed medications. Itraconazole has been associated with rare cases of serious hepatotoxicity, including liver failure and death, and should be discontinued if signs or symptoms of liver disease occur.

SOURCE Mylan Inc.

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