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Mylan Launches Generic Version of Provigil® Tablets

PITTSBURGH, Aug. 10, 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 Modafinil Tablets USP, 100 mg and 200 mg. This product is the generic version of Cephalon's Provigil® Tablets and is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea and shift work disorder.(1)

Mylan CEO Heather Bresch commented: "Mylan is pleased to bring a generic version of Provigil Tablets to the U.S. market prior to the expiration of the first-filer's 180-day marketing exclusivity period. This launch represents Mylan's continued commitment to expanding access to high quality, more affordable medicine, and we are pleased to do our part in helping to meet patients' unmet needs."

Modafinil Tablets, 100 mg and 200 mg, had U.S. sales of approximately \$1.3 billion for the 12 months ending June 30, 2012, according to IMS Health. Mylan is launching this product immediately.

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

(1) Modafinil has been associated with serious rashes requiring hospitalization and hypersensitivity reactions. It is not approved for use in pediatric patients for any indication.

SOURCE Mylan Inc.

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