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Mylan Launches Generic Version of Atacand HCT®

-Company awarded 180 days marketing exclusivity on 32/25 mg strength-

PITTSBURGH, Dec. 5, 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 Candesartan Cilexetil and Hydrochlorothiazide Tablets, 16/12.5 mg, 32/12.5 mg and 32/25 mg.

This product is the generic version of AstraZeneca's Atacand HCT®, and is indicated for the treatment of hypertension. This fixed dose combination is not indicated for initial therapy.(1)

Mylan was the first company to have submitted a substantially complete ANDA to the FDA containing a Paragraph IV certification for Candesartan Cilexetil and Hydrochlorothiazide Tablets, 32/25 mg, and was awarded 180 days of generic drug marketing exclusivity for this product strength. Mylan is shipping all approved strengths of this product immediately.

Atacand HCT had U.S. sales of $56.3 million for the 12 months ending Sept. 30, 2012, according to IMS Health.

Currently, Mylan has 178 ANDAs pending FDA approval representing $80.1 billion in annual sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing $21.2 billion in annual brand sales, for the 12 months ending June 30, 2012, 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) Candesartan Cilexetil and Hydrochlorothiazide Tablets can cause injury and death to the developing fetus and therefore should be discontinued if pregnancy occurs. This product is contraindicated in patients who are hypersensitive to any component of this product or to other sulfonamide-derived drugs and in patients with anuria. Other precautions include: excessive reductions in blood pressure, decreased renal function, allergic reactions, exacerbation or activation of systemic lupus erthematosus, drug interactions with lithium, potassium and electrolyte abnormalities, visual changes and metabolic disturbances. If any of these conditions occur or are suspected, medical attention should be sought.

SOURCE Mylan Inc.