



August 17, 2012

## **Mylan Launches Generic Actoplus Met® Tablets and Generic Actos® Tablets**

### **-Company granted 180 days marketing exclusivity on both products-**

PITTSBURGH, Aug. 17, 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 Pioglitazone Tablets USP, 15 mg, 30 mg and 45 mg. Previously, the company also received final approval from the FDA for its ANDA for Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, 15 mg/500 mg and 15 mg/850 mg. These products are the generic versions of Takeda Pharmaceutical Company's Actos® Tablets and Actoplus Met® Tablets, respectively, and are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.(1) The FDA has awarded Mylan 180 days of generic marketing exclusivity on both of these products.

Mylan CEO Heather Bresch commented: "Mylan's immediate launch of these products is representative of the company's ongoing commitment to expand access to high quality, more affordable medicines. A crucial part of setting new standards in health care includes meeting patients' unmet needs, and we look forward to continuing to grow our portfolio of products for patients living with diabetes."

Pioglitazone Tablets USP, 15 mg, 30 mg and 45 mg, had U.S. sales of approximately \$2.7 billion, and Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, 15 mg/500 mg and 15 mg/850 mg, had U.S. sales of approximately \$413 million for the 12 months ending June 30, 2012, according to IMS Health.

Currently, Mylan has 166 ANDAs pending FDA approval representing \$75.6 billion in annual sales, according to IMS Health. Thirty-four of these pending ANDAs are potential first-to-file opportunities, representing \$21.7 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](http://mylan.com)

This press release includes statements that constitute "forward-looking statements," including with regard to the launch of the products, marketing exclusivity, and expansion expectations. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: the use of legal, regulatory and legislative strategies by competitors or other third parties to delay or prevent product introductions; the impacts of competition; changes in economic and financial conditions affecting the Company's business; uncertainties and matters beyond the control of management; and the other risks detailed in the Company's periodic filings with the Securities and Exchange Commission. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release.

(1) Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets and Pioglitazone Hydrochloride Tablets can cause or exacerbate congestive heart failure in some patients and therefore patients should be monitored for signs and symptoms of heart failure. Patients with symptomatic heart failure should not take this medication. Lactic acidosis can also occur as a result of Metformin accumulation. Patients that experience malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress should seek medical attention.

SOURCE Mylan Inc.

News Provided by Acquire Media