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Mylan Launches Generic Xeloda® Tablets

PITTSBURGH, Aug. 11, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that it has launched Capecitabine Tablets USP, 150 mg and 500 mg, the generic version of Genentech's Xeloda® Tablets. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is indicated as monotherapy, adjuvant therapy and combination therapy for certain types of breast, colon and colorectal cancers.(1)

CEO Heather Bresch commented, "The approval of this product, one of a number of key approvals that had been pending with FDA, adds an important product to our broad and growing oncology franchise. We look forward to bringing a lower cost generic version of this product to patients."

Capecitabine Tablets USP, 150 mg and 500 mg, had U.S. sales of approximately $773.8 million for the 12 months ending June 30, 2014, according to IMS Health.

Currently, Mylan has 296 ANDAs pending FDA approval representing $106 billion in annual brand sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing $25.0 billion in annual brand sales, for the 12 months ending Dec. 31, 2013, 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 excellence 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 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% 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 140 countries and territories. Our workforce of more than 20,000 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) Patients taking Capecitabine in combination with anticoagulation drugs, like warfarin and phenprocoumon, should have their coagulation response monitored frequently. Capecitabine is not indicated in patients with dihydropyrimidine dehydrogenase deficiency, severe renal insufficiency or a known hypersensitivity to capecitabine or any of its components.

This press release includes statements that constitute "forward-looking statements," including with regard to sales of products. 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: strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; and the other risks detailed in the company's 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.

SOURCE Mylan Inc.