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Mylan-Biocon Receive First Indian Biosimilar Regulatory Approval for Herceptin®

PITTSBURGH, Nov. 25, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its partner Biocon has received approval for a Mylan-Biocon trastuzumab product from the Drug Controller General of India. This is the first regulatory approval for a Mylan-Biocon developed biosimilar product. The product is a biosimilar to Roche's Herceptin®, indicated for the treatment of HER2 overexpressing breast cancer. Mylan intends to market its trastuzumab product under the trade name Hertraz.

Mylan CEO Heather Bresch commented, "This regulatory achievement marks another Mylan first and underscores our commitment to, and confidence in, our biologic development program with Biocon and our belief that these products will become a global growth driver for Mylan over the long-term. We expect to launch our trastuzumab product in India early next year, marking our first launch of a biologic, and we look forward to bringing a high quality, affordable product to patients in India who need it. This launch also further strengthens our expanding commercial presence in India, as we enter the oncology and critical care segments."

Trastuzumab is one of the five biologic products Mylan is developing in partnership with Biocon for the global marketplace. Mylan has exclusive commercialization rights for biosimilar trastuzumab in the U.S., Canada, Japan, Australia, New Zealand and in the European Union and European Free Trade Association countries and co-exclusive commercialization rights with Biocon for product in India. Mylan expects to launch trastuzumab in India early in 2014.

According to IPSOS, trastuzumab had sales in India of approximately \$21 million for the 12 months ended Dec. 31, 2012.

This press release includes statements that constitute "forward-looking statements," including with regard to product approvals and regulatory matters. 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 impact and effects of legal or regulatory proceedings; uncertainties and matters beyond the control of management; 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.

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 1,200 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

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