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Mylan Launches First Trastuzumab Biosimilar, Hertraz™, in India

Availability of 150 mg formulation increases dosing convenience and flexibility

MUMBAI and PITTSBURGH, Feb. 3, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL), one of the world's leading generic and specialty pharmaceutical companies, today announced that its subsidiary, Mylan Pharmaceuticals Private Limited, has launched the world's first trastuzumab biosimilar in India. The product, which will be marketed by Mylan under the brand name Hertraz™, is a biosimilar to Roche's Herceptin®. Hertraz is indicated for the treatment of HER2-positive metastatic breast cancer and is available in two strengths, 440 mg and 150 mg.

(Photo - <http://photos.prnewswire.com/prnh/20140203/NE57237>)

Mylan CEO Heather Bresch commented: "Mylan is excited to offer Hertraz to the thousands of women in India suffering from metastatic breast cancer who are in need of a high quality, more affordable treatment option. The launch of Hertraz not only represents a significant milestone in our biosimilars development program with Biocon, but, more importantly, supports our mission to expand access to high quality medicine around the world and demonstrates our progress against one of Mylan's key future growth drivers."

Mylan President Rajiv Malik added: "The launch of Hertraz is of particular significance as it represents both Mylan's first biosimilar and the world's first trastuzumab biosimilar. We look forward to expanding our portfolio of high quality and affordable biosimilar offerings, particularly in the oncology care segment, in India and around the world in the coming years."

Hertraz was approved by the Drug Controller General of India. In support of this approval, Mylan conducted an extensive series of physicochemical and functional assays to demonstrate similarity to the reference brand Herceptin. These analytical methodologies confirmed the high degree of molecular similarity as well as biological activity of Hertraz. In addition, Mylan conducted a multi-center clinical trial to demonstrate comparable safety and efficacy to the reference product.

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.

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

Currently, Mylan has 187 ANDAs pending FDA approval representing \$93.7 billion in annual sales, according to IMS Health. Forty-one of these pending ANDAs are potential first-to-file opportunities, representing \$24.1 billion in annual brand sales, for the 12 months ending June 30, 2013, according to IMS Health. When including ANDAs associated with Mylan's recent acquisition of Agila, the company now has a total of 287 ANDAs pending FDA approval.

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

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