

Mylan launches first biosimilar in India

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Mylan Pharmaceuticals, Indian subsidiary of leading generic company - Mylan Inc, has launched the world's first trastuzumab biosimilar in India. The product, 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.

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 US, Canada, Japan, and 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 President, Mr 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.