



Press Release

## Biocon & Mylan Receive Indian Regulatory Approval for Biosimilar Trastuzumab for Treating Breast Cancer

Bangalore, India: Nov 26, 2013

Biocon Ltd, Asia's premier biotechnology company, announced today that it has received Marketing Authorization from the Drugs Controller General of India (DCGI) for its **biosimilar Trastuzumab** being developed jointly with Mylan, for the treatment of Her 2+ metastatic breast cancer.

The regulatory approval for **biosimilar Trastuzumab** in India is an extremely important milestone for Biocon as it is the world's first biosimilar version of Herceptin® to be brought to the market. The **biosimilar Trastuzumab** will be marketed in India under the brand name of CANMAb™ by Biocon and is expected to be available to Indian patients in Q4 FY14.

Breast cancer is one of the most common types of cancer in India with over 100,000 new breast cancer patients being diagnosed with this disease every year. The cost of Biologics in cancer treatment is extremely high which makes access unaffordable to a large patient pool. Biosimilar Trastuzumab will offer an alternative affordable option thereby enhancing access to treatment for cancer patients in India and the world over.

**Kiran Mazumdar Shaw, Chairperson & Managing Director, Biocon Ltd**, said, *"This is a major milestone for both partners as it is the world's first biosimilar Trastuzumab to be accorded regulatory approval. We plan to make CANMAb™ available to Indian patients in Q4 FY14. The meticulous development of this important cancer drug has involved extensive product characterization and clinical trials to demonstrate comparability and similarity in PK (pharmacokinetic), safety, efficacy and immunogenicity against the innovator product. We are committed to affordable cancer care and believe that biosimilar Trastuzumab will expand patient access to this life saving drug. The Indian approval is an encouraging milepost as we plan to leverage this data to support regulatory filings in several countries across the globe."*



The global sales for Trastuzumab stood at ~US\$ 6.4 bn in 2012, while in India it recorded sales of ~US\$21 Mn.

Since 2009, Biocon and Mylan have been co-developing a high value portfolio of Biosimilar monoclonal antibodies and complex biologics, comprising Trastuzumab, Pegfilgrastim, Bevacizumab, Adalimumab and Etanercept. The Innovator product sales of these products in 2012 were pegged at ~ US\$ 34 billion. The patent expiry of these products in regulated markets is expected from 2015 onwards.

In 2013, this partnership was extended to co-development of Biosimilar Insulin analogs for the global markets. The overall global opportunity for biosimilars is estimated to be US \$ 22 billion by 2020.

*# Herceptin is a registered brand of Roche*

#### **About Biocon**

Established in 1978, Biocon Limited, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and Asia's leading biotechnology company with a strategic focus on biopharmaceuticals and research services. It is a fully integrated, innovation-driven biopharma enterprise offering affordable solutions for chronic diseases to patients worldwide. Biocon's robust product portfolio includes the world's first Pichia-based recombinant human Insulin, INSUGEN<sup>®</sup>, Glargine, BASALOG<sup>®</sup> and India's first biologic BioMAb-EGFR<sup>™</sup> for head & neck cancer. It has now successfully developed its second novel biologic Itolizumab, a 'first in class' anti-CD6 monoclonal antibody, introduced as Alzumab<sup>™</sup> for psoriasis in India, in 2013. Visit: [www.biocon.com](http://www.biocon.com)

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