



Press Release

Biocon introduces **CANMAb™** - World's First Biosimilar Trastuzumab for Treating Breast Cancer in India

Bangalore, India: Jan 18, 2014

Biocon Ltd, Asia's premier biotechnology company, today introduced **CANMAb™** (150 mg/440 mg), a biosimilar trastuzumab for the treatment of HER2-positive metastatic breast cancer in India. **CANMAb™**, developed jointly by Biocon and Mylan under a global partnership, is the world's first biosimilar version of *Herceptin* and is being introduced for the benefit of patients in India.

Breast cancer is the most prevalent cancer among Indian women ahead of cervical cancer and **CANMAb™** will offer a high quality, more affordable option to breast cancer patients in India. Approximately, 1.5 lakh new patients are diagnosed with breast cancer every year in India, of which nearly 25% cases are HER2-positive and eligible for treatment with **CANMAb™**. Lack of affordable treatment options has limited the extent of HER2 testing and it is believed that the proportion of HER2-positive patients is probably higher.

Kiran Mazumdar-Shaw, Chairperson & Managing Director, Biocon Ltd, said, "*Biocon intends to make a significant difference in the treatment paradigm for HER2-positive breast cancer in India by enhancing access to more affordable treatment with **CANMAb™** (biosimilar trastuzumab), which offers the same level of safety and efficacy as the reference product. The launch of **CANMAb™** in India is an important milestone for our biosimilars program and demonstrates our ability to deliver on our promise of affordable innovation with a high quality, world-class product.*"

CANMAb™ is a targeted therapy for the treatment of HER2-positive breast cancer and acts by interfering with HER2 protein production and stopping the growth of cancer cells. It is easy to administer and will be given intravenously, once every 3 weeks or on a weekly basis depending on the patient's condition. Unlike the product currently available in the market, both 150 and 440 mg formulations of **CANMAb™** can be stored for 1 month which is an important offering for patients in India, as it will ensure that there is no under dosing or wastage of drug which is quite common today.

CANMAb™ is being manufactured at Biocon's biologics facility in Bangalore and will be available to patients around the first week of February 2014. **CANMAb™** will be available at



about 25% discount to the current list price of the reference product in India, which is already significantly lower than its price in developed markets. In addition, CANMAb's 150 mg formulation, priced at Rs 19,500/vial, will allow extra savings to patients as they can buy smaller quantities as per their requirement.

Developing a quality biosimilar monoclonal antibody requires high technical skills, significant investments in clinical development and manufacturing and long gestation periods resulting in significantly higher costs of development and manufacturing compared to common chemistry-based pharmaceutical drugs.

India is witnessing increased usage of targeted therapies like biologics as compared to cytotoxics. This trend is likely to continue given the improved treatment outcomes.

The relatively higher cost of developing biologics means these drugs remain unaffordable for a large section of the population. The introduction of high quality biosimilars like **CANMAb™** will make access more affordable and thereby expand the patient pool.

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

Biocon: A Leading Oncology Company

Biocon today is recognised as one of the leading oncology companies in the country. It has delivered a novel biologic **BioMAb EGFR™** for head & neck cancer in India.

Till date, over 5,500 patients have benefitted from this novel product.

Notes to the Editor:

CANMAb™ Development

CANMAb™ (biosimilar trastuzumab) is being made available to cancer patients following a multi-centric clinical trial in India to demonstrate comparability and similarity in PK (pharmacokinetics), safety, efficacy and immunogenicity with the reference product. This trial followed international regulatory and quality guidelines to ensure the data generated are of high quality and reliability. Extensive physico-chemical and biological characterization data has been generated using multiple high end techniques for demonstrating biosimilarity of **CANMAb™** at a molecular level.

The Biocon-Mylan joint development program also includes additional global clinical development, which is underway at multiple sites across the globe.



Biologics improve survival rate

Standard treatments for breast cancer include surgery, chemotherapy, hormone therapy and targeted therapies, including biologics. The survival rate for breast cancer patients in the US has improved to nearly 90% after the introduction of biologics, improved screening, and other treatment enhancements.

#Herceptin is a registered brand of Roche

Source: GLOBOCAN 2012 database, NIH Cancer fact sheet 2010

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[®], Glargine, BASALOG[®] and India's first biologic BioMAb-EGFR™ for head & neck cancer. It has also successfully developed its second novel biologic Itolizumab, a 'first in class' anti-CD6 monoclonal antibody, introduced as Alzumab™ for psoriasis in India, in 2013. Visit: www.biocon.com

For further information: canmab.patientcontact@biocon.com	
Media Contacts	
Seema Ahuja Head-Corporate Communications M:+91 9972317792 seema.ahuja@biocon.com	Rumman Ahmed Manager-Corporate Communications +91 9845104173 rumman.ahmed@biocon.com
Medical Contact Dr. Nagaraj B Malipatil, Medical Advisor, Biocon Onco-therapeutics M: +91 8067751107 nagaraj.malipatil@biocon.com	
Investor Relations	
Saurabh Paliwal Head-Investor Relations +91 9538380801 saurabh.paliwal@biocon.com	Sweta Pachlangiya Deputy Manager-Investor Relations +91 9686509372 sweta.pachlangiya@syngeneintl.com