

Biocon's Statement on Delhi High Court Interim Order on Trastuzumab on March 3, 2017

Bengaluru, Karnataka, India, March 03, 2017-

"We welcome the Delhi High Court interim order passed today permitting Biocon to manufacture and sell its biosimilar Trastuzumab, CANMAb™ without any restrictions for all three indications namely Her2 Metastatic Breast Cancer (MBC), Early Breast Cancer (EBC) and Metastatic Gastric Cancer (MGC). The Division Bench not only has stayed the operation of the order of April 2016, but also pronounced in court that Biocon can use the Package Insert for all three indications including the publically available data of the reference product therein as it has been approved by the Drugs Controller General of India (DCGI)."

We see this as a significant positive development which will pave the way for greater access to affordable biosimilar Trastuzumab for cancer patients in India. Biocon's CANMAb™ has been developed as per existing Indian biosimilar guidelines and has been introduced in the market in 2014, post clinical studies and necessary regulatory approvals. Since then it has been providing an affordable alternative to Her2 positive breast cancer patients in India."

Company Spokesperson-

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About Biocon:

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and fully-integrated, innovation-led biopharmaceutical company. As an emerging global biopharmaceutical enterprise serving customers in over 100 countries, it is committed to reduce therapy costs of chronic diseases like diabetes, cancer and autoimmune. Through innovative products and research services it is enabling access to affordable healthcare for patients, partners and healthcare systems across the globe. It has successfully developed and taken a range of Novel Biologics, Biosimilars, differentiated Small Molecules and affordable Recombinant Human Insulin and Analogs from 'Lab to Market'. Some of its key brands are INSUGEN® (rh-insulin), BASALOG® (Glargine), CANMAb™ (Trastuzumab), BIOMAb-EGFR™ (Nimotuzumab) and ALZUMAb™ (Itolizumab), a 'first in class' anti-CD6 monoclonal antibody. It has a rich pipeline of Biosimilars and Novel Biologics at various stages of development including Insulin Tregopil, a high potential oral insulin. www.biocon.com

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