

## Press Release

# Biocon-Mylan Programs Make Progress

## PEG-G-CSF and Adalimumab enter Phase 3 clinical trials; Patient recruitment for one Insulin Glargine Phase 3 study completed

Bangalore, India: May 07, 2015

Biocon, Asia's premier biotechnology company, announced today that it has made clinical progress in its partnered programs with Mylan. The partnership has a strong portfolio of generic insulin analogs and biosimilars including Monoclonal Antibodies (MAbs) and recombinant proteins at various stages of development.

### Biosimilars

Two molecules **Pegfilgrastim** (PEG-G-CSF) and **Adalimumab** have entered global Phase 3 clinical trials. While the **PEG-G-CSF** trial is well underway the **Adalimumab** trial has been recently initiated.

In addition, the Phase 3 global clinical trial for **Trastuzumab** is progressing in more than 100 sites around the world. An initial ROW focused Phase 3 trial for **Bevacizumab** is also underway.

### Generic Insulin Analogs

Two global clinical trials for generic Insulin **Glargine** initiated in 2014, have also made significant progress. The patient recruitment for Type-1 diabetes study has been completed ahead of schedule, while the recruitment for Type-2 diabetes study is expected to be completed by July 2015.

**Dr Arun Chandavarkar, CEO & Joint Managing Director, Biocon**, said, "The advancement of these programs in the clinic represents significant progress towards providing these high quality biologics to patients across the world. I am confident that, together with our partner Mylan, we can build a strong global presence in generic Insulin analogs and biosimilars like monoclonal antibodies and recombinant proteins to address the need for affordable access to these biologics."



As part of a shared commitment to provide access to high-quality and affordable biopharmaceuticals, Biocon and Mylan have established a strong collaborative R&D partnership for both generic insulin analog products and a high-value portfolio of biosimilars for oncology and autoimmune indications.

Biocon today has one of the largest generic insulin analogs and biosimilars portfolio in advanced stages of development with five molecules in Phase 3 clinical trials, viz. **Glargine, Pegfilgrastim, Adalimumab, Bevacizumab and Trastuzumab.**

As we move into FY16, we clearly see our biosimilar strategy playing out with greater clarity, credibility and traction visible across our portfolio of Biologics as they advance in clinical development. We continue to make investments in R&D as a strong future value driver for Biocon.

#### **About Biocon Limited**

*Biocon Limited, publically 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 85 countries, it is committed to reduce therapy costs of chronic diseases like autoimmune, diabetes, and cancer. 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 a high potential oral insulin. Visit: [www.biocon.com](http://www.biocon.com)*

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