

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

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Disclaimer:

Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and

pharmaceuticals industries, increasing competition in and the conditions of the Indian biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither our company, our directors, nor any of our affiliates, have any obligation to update or otherwise revise any statements reflecting circumstances arising after this date or to reflect the occurrence of underlying events, even if the underlying assumptions do not come to fruition.

Disclaimer:

Syngene International Limited is proposing, subject to receipt of requisite approvals, market conditions and other considerations, to make an initial public offering of its Equity Shares and has filed a Draft Red Herring Prospectus with the Securities and Exchange Board of India (“SEBI”). The Draft Red Herring Prospectus is available on the website of the SEBI and the websites of Axis Capital Limited, Credit Suisse Securities (India) Private Limited and Jefferies India Private Limited. Investors should note that investment in Equity Shares involves a high degree of risk and for details should refer to the Red Herring Prospectus/Prospectus which may be filed with the Registrar of Companies, Bangalore in the future, including the section titled “Risk Factors”.

This press release is not an offer of the Equity Shares for sale in the United States. Any public offering of the Equity Shares to be made in the United States will be made by means of a prospectus that may be obtained from the Company or the selling shareholder and that will contain detailed information about the company and management, as well as financial statements.

The Equity Shares have not been, and will not be, registered under the Securities Act or any other applicable law of the United States and, unless so registered, and may not be offered or sold within the United States, except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and applicable state securities laws. Accordingly, the Equity Shares are only being offered and sold (i) within the United States only to persons reasonably believed to be “qualified institutional buyers” (as defined in Rule 144A under the Securities Act and referred to in the Draft Red Herring Prospectus as “U.S. QIBs”, for the avoidance of doubt, the term U.S. QIBs does not refer to a category of institutional investor defined under applicable Indian regulations and referred to in the Draft Red Herring Prospectus as “QIBs”) in transactions exempt from, or not subject to, the registration requirements of the Securities Act, and (ii) outside the United States in reliance on Regulation S under the Securities Act.