



Press Release

Biocon's Insulin Glargine Receives Regulatory Approval in Japan

Bangalore, India, March 28, 2016

Biocon Ltd. (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceutical company, today announced that the Ministry of Health, Labour and Welfare (MHLW) of Japan has approved its biosimilar Insulin Glargine. This is a significant achievement for Biocon and its commercial partner, FUJIFILM Pharma Co. Ltd (FFP) as it endorses our endeavor to bring high quality, yet affordable, world class products to diabetes patients in Japan.

The product is a ready-to-use, prefilled disposable pen with 3 ml of 100IU Insulin Glargine, expected to be launched in Q1 FY17, aiming to capture a significant share of the Japanese Glargine market of US\$ 144 Mn[^], which is the second largest market outside of North America & Europe and is largely dominated by disposable pens.

The approval for Insulin Glargine has been obtained post successful completion of initial development by Biocon and local Phase III Clinical Studies in over 250 Type 1 Diabetes patients by our partner in Japan. Biocon's manufacturing facilities for Insulin Glargine, and its state-of-the-art disposable pen assembly facility, were inspected and approved by the Japanese regulatory authorities. This pen assembly facility was inaugurated in September 2015 for the launch of Biocon's Insulin Glargine pen branded as 'Basalog One' in India.

Biocon Chairperson & Managing Director Kiran Mazumdar-Shaw said: *"The Insulin Glargine approval in the highly regulated market like Japan, marks a huge credibility milestone for Biocon. We see this as a significant achievement in our journey of making global impact in diabetes management through our affordable biosimilar insulins. We hope to enable the Japanese government to bring down its healthcare expenditure on diabetes with the use of this cost effective, high quality biosimilar Insulin Glargine."*

The Per capita spending on pharmaceuticals in Japan is the second highest[#] among OECD countries after the US, and the government is striving to rationalize healthcare spends by encouraging the entry of high quality yet affordable follow-on biologics. This approval will enable Biocon to address the growing needs of diabetes patients in Japan which reported 7.2 million* cases in 2015.

Biocon is recognized as Asia's largest insulins producer and has been committed to affordable diabetes management through rh-Insulin (Insugen[®]) and Insulin Glargine (Basalog[®]) in India



and several emerging markets. The company currently has marketing approvals in over 60 countries for rh-Insulin and in over 20 countries for Insulin Glargine. It is also developing Insulin Glargine for the developed markets outside of Japan in collaboration with Mylan.

[^]Source: IMS March 2015 ^{*}Source: IDF [#]Source: OECD data

About Biocon Ltd

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 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 high potential oral insulin. Visit: www.biocon.com

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.

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