



Press Release

## **Biocon Inks Co-Development & Commercialization Agreement with Lab PiSA for rh- Insulin in USA**

**Bangalore, India, March 17, 2016**

**Biocon Ltd.** (BSE code: 532523, NSE: BIOCON) Asia's premier biopharmaceuticals company, announced today that its wholly owned subsidiary Biocon SA has entered into an agreement with Laboratorios PiSA S.A. de C.V (PiSA) of Mexico for the co-development and commercialization of generic recombinant human insulin (rh-insulin) for the US market.

This collaboration is a part of Biocon's strategy to address the large demand for generic rh-insulin in the US, which accounts for over 40% of the global sales of US \$5 billion.

This is an extension of the Company's long standing relationship of over 10 years with its trusted partner, PiSA, who has a dominant position in insulins in Mexico. Biocon's Insulin Glargine was the first to be approved in Mexico in 2015, as per the new bio-comparable approvals pathway. Both companies are committed to providing affordable access to insulins to patients.

This is a cost and profit sharing agreement with Biocon responsible for clinical development, regulatory approvals, and commercialization of the product in the US.

This partnership will leverage Biocon's manufacturing facilities for the drug substance and PiSA's drug product facilities in Mexico. Furthermore, this arrangement will take advantage of PiSA's proximity to the US market and Mexico's NAFTA membership, which will ensure an efficient and optimal supply chain to address the needs of the US healthcare system for an affordable, high quality rh-insulin.

Biocon's global clinical development experience with Insulin Glargine for the US will be a useful precedent in developing rh-insulin for the US market. Through this collaboration, we will introduce rh-insulin under the Biocon brand to address the US \$2 bn market opportunity in the US.

**Biocon Chairperson & Managing Director Kiran Mazumdar-Shaw** said: *"Our partnership with PiSA demonstrates our commitment to provide access to affordable insulins to patients in the US. This collaboration will enable us to manufacture the rh-insulin drug product at PiSA's facilities in Mexico and commercialize it under Brand Biocon in the US market, which has a huge diabetes burden with over 1.4 million\* people diagnosed with diabetes every year."*

**PiSA Chairman & President Carlos Alvarez Bermejillo** stated *"Applying PiSA's world class, state of the art sterile injectable and biotechnology development & manufacturing capabilities to contract manufacture Biocon's generic rh- insulin products represents a major milestone in PiSA's strategy to enter the US sterile injectable market"*.

*"PiSA has been marketing insulin products based on Biocon's high quality API for many years, hence this partnership to develop generic rh- insulin products represents the natural progression of a strong relationship between the two firms"*, he added.



Biocon is recognized as Asia's largest insulins producer and has been committed to provide 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.

*\*Source: American Diabetes Association*

### 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 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™(Itoлизumab), 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](http://www.biocon.com)

### About Grupo Pisa

Grupo Pisa is a privately owned group of companies based in Guadalajara, Mexico with 14 manufacturing facilities and over 16,000 employees throughout Mexico. It is a fully integrated provider of products and services for human and animal health whose flagship product, *Electrolit*, recently entered the US market as a rehydration beverage. Over the past 75 years, Pisa has grown to be Mexico's largest and leading pharmaceutical company that manufactures over 1,500 products across 17 specialty therapeutic lines.

Pisa has been marketing insulin products based on Biocon's high quality API for many years so the partnership to develop biosimilar insulin products represents the natural progression of a strong relationship between the two firms.

### 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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