

Biocon inks co-development & commercialization agreement with Lab PiSA for rh- Insulin in USA

17 March 2016 | News | By BioSpectrum Bureau

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Biocon Ltd. announced 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 \$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.