

Biocon Announces Positive Results from its Global Phase 3 study with Recombinant Human Insulin

Study demonstrates comparable safety and efficacy with the innovator product

Bangalore, India: October 31, 2012

Biocon, Asia's premier biotechnology Company, announced today that the Global Phase 3 study for its Recombinant Human Insulin (INSUGEN®), in Type 1 diabetes mellitus (T1DM) patients, demonstrates comparable safety and efficacy with the innovator product.

This multi-center, randomized study was conducted in nearly 300, T1DM patients, to compare efficacy, safety and immunogenicity of Biocon's Regular human Insulin (Insugen R®) and Isophane human Insulin (Insugen N®) against the innovator products (Actrapid® and Insulatard®) sourced from Europe. The trial met its efficacy end-point by demonstrating non-inferiority in HbA1c endpoint at 6 months. Immunogenicity and safety as evaluated by hypoglycemic events at the 6 month time point were also similar.

The Part 2 of the study to demonstrate additional safety and immunogenicity over one year is ongoing and is expected to be completed by next year with the final results expected in H1, FY14.

Data from this ongoing study along with extensive physico-chemical & biological characterization and PK-PD (pharmacokinetic & pharmaco-dynamic) data generated to date comparing Insugen-R® & Insugen-N® with the innovator products will enable Biocon to submit a robust dossier for marketing authorization in EU and other global markets.

Commenting on these results, Ms. Kiran Mazumdar-Shaw, Chairman & Managing Director, Biocon said, *“The positive outcome of this global phase 3 study is a significant milestone in our global insulins development program and will enable regulatory approvals of our recombinant human insulin products across developed and emerging markets. Human insulin is a widely accepted component of insulin therapy for diabetes patients and Biocon’s human insulin, will present an affordable alternative to the patients worldwide. These data along with the recent PK-PD data for our insulin glargine (BASALOG®) demonstrate our commitment to pursue our global insulins strategy and deliver affordable therapy to the patients.”*

“This data along with extensive characterization and PK-PD data generated to date with Biocon’s regular and isophane insulin demonstrate comparability with the innovator products”, said **Dr. Abhijit Barve, President R&D of Biocon.** *“This was our first global study for rh-Insulin and we are pleased with the outcome. These data and our recent positive PK-PD data for Biosimilar Glargine enable us to pursue our global development strategy for Biosimilar Insulins.”*

About Human Recombinant Insulins

Insugen R® is short-acting human insulin and offers post meal control of glucose while Insugen N® is long-acting human insulin and offers basal control of glucose levels. Human recombinant insulin is used as a basal-bolus regimen or pump regimen and is most widely used by Type 1 and Type 2 diabetics in most parts of the world. Biocon’s INSUGEN® is currently marketed in various countries and these data will reinforce the confidence of physicians & diabetes care providers in INSUGEN® & other products in the insulin portfolio.

Actrapid® and Insulatard® are registered brands of Novo Nordisk

About Biocon Limited

Biocon Limited (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India’s premier biotechnology company with a strategic focus on biopharmaceuticals and research services. Established in 1978 by Dr. Kiran Mazumdar-Shaw, the Group is an integrated, innovation-driven



healthcare enterprise with offerings that traverse the entire drug development value chain. Balancing its novel molecule research pipeline with a diversified product portfolio, Biocon delivers affordable solutions to partners and customers in over 75 countries across the globe. Many of these products have USFDA and EMA acceptance. Stellar products from Biocon's stable include the world's first Pichia-based recombinant human Insulin, INSUGEN® and glargine, BASALOG® coupled with a state of the art insulin pen device, INSUPen® and India's first indigenously produced monoclonal antibody BioMAb-EGFR®. With a team of over 6500 employees, Biocon has been recognized amongst the 'Top 20' Global Employers in biopharma sector. www.biocon.com

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