Press Release

Biocon announces positive results from its Phase 1 Comparative PK-PD Study with Biosimilar Insulin Glargine

Bengaluru, India: July 25, 2012:

Biocon, Asia's premier biotechnology company, today announced positive results from a Phase 1 comparative study conducted in Germany of its Biosimilar Insulin Glargine in Type 1 Diabetes Mellitus (T1DM) patients.

This randomized, double-blind, euglycemic clamp study was conducted in T1DM patients to evaluate pharmacokinetic (PK) and pharmacodynamic (PD) equivalence of Biocon's Insulin Glargine against the innovator product (Lantus®). The trial met all its primary and secondary endpoints.

These encouraging results indicate that Biocon's Insulin Glargine is equivalent to the innovator product in terms of PK and PD. These robust clinical data along with extensive physicochemical and biological characterization data generated to date between Biocon's Insulin Glargine and the innovator product will enable Biocon to start its Phase 3 program in the U.S. and E.U. aimed at demonstrating comparative safety, efficacy and immunogenicity in diabetes mellitus patients.

"*This study clearly demonstrates that Biocon's Insulin Glargine is bioequivalent to LANTUS®, so that both insulins will have the same effect when used in identical doses",* **said Dr Tim Heise, CEO Science & Administration of Profil® in Neuss, Germany, and Principal Investigator of the study.** "*The study had a robust design, was conducted under the international standards of ICH/GCP (International Conference of Harmonization/Good Clinical Practice) and used an automated euglycemic glucose clamp technique which is the gold standard for assessment of the pharmacodynamic properties of insulin preparations. Biocon's Insulin Glargine and LANTUS® were very well tolerated; without any serious adverse event observed during the four month study period. I am very confident that based on these data, regulators will accept the pharamcokinetic and pharmacodynamic biosimilarity of Biocon's Insulin Glargine and LANTUS®."*

Expressing her satisfaction with the clinical development progress Ms. Kiran Mazumdar-Shaw, Chairman & Managing Director, Biocon said, "*Insulin Glargine is a key product in our growing portfolio of biosimilar insulins. The successful outcome of this critical Phase 1 study demonstrates our strong commitment towards developing high quality biosimilars and paves the way for the Phase 3 program of Biosimilar Insulin Glargine that will enable regulatory approvals of our product across developed and emerging markets. These data will further increase the confidence of physicians prescribing BASALOG® and contribute to our vision to have market leadership in biosimilar products.*"

Biocon intends on conducting the Phase 3 global program using internal resources and will be engaging with several potential regional and global partners to ensure affordable innovation is accessible to all patients across the globe.

About Phase 1 Clinical study of Biocon's Insulin Glargine

This cross over trial conducted in Germany, comparing 100 IU/ml of Lantus® and Biocon's Insulin Glargine to establish PK and PD equivalence was conducted in T1DM patients. The study was sufficiently powered to establish bioequivalence. The primary endpoints for PK (Insulin-AUC and Insulin-C_{max}) and PD (Glucose Infusion Rate GIR_{max} and GIR-AUC) met the pre-specified equivalence margins. Multiple secondary endpoints for PK and PD were also met.

About Insulin Glargine

Insulin glargine is a long acting analogue of human insulin for the treatment of Type 1 and Type 2 Diabetes Mellitus patients. It differs from insulin with respect to three amino acids such that the amino acid asparagine at position A21 is replaced by glycine and two arginine amino acids are added to the c-terminal of the B-chain.

BASALOG®- Biocon Biosimilar Insulin Glargine
Lantus®- Registered Trademark of Sanofi Aventis

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 biopharma product portfolio, Biocon delivers affordable solutions to partners and customers in over 70 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 delivery device, INSUPen® and India's first indigenously produced monoclonal antibody BioMAb-EGFR® for head and neck cancer. www.biocon.com

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