

Biocon gets positive results in insulin glargine study

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Bangalore: Biocon has announced positive results from a phase I 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 thus indicating that Biocon's Insulin Glargine is equivalent to the innovator product in terms of PK and PD.

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.

Dr Kiran Mazumdar-Shaw, chairman & managing director, Biocon, mentioned that Insulin Glargine is a key product in Biocon's 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 in the U.S. and E.U, 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," she added.

Biocon intends on conducting the phase III 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.

In related news, Bicon released its Q1 FY13 financials reflecting a strong performance across business verticals. The Biopharma Business grew 23% YoY along with the Branded Formulations' growing at a robust 52% YoY with the main drivers being Oncology, Diabetology and Comprehensive Care. The combine contract research services of Syngene and Clinigene grew at 40% YoY. Additionally the EBITDA and PAT margins stood at 23% and 13% respectively being largely impacted by increased R&D spend.