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Biocon insulin study gives positive results

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Biocon recombinant human insulin study gives positive results

Bangalore: The global phase III study for Biocon's recombinant human insulin (Insugen(R)), in Type 1 diabetes mellitus patients, has demonstrated comparable safety and efficacy with the innovator product. Bangalore-headquartered Biocon is one of Asia's premier biotechnology companies.

Research and development expenditure has risen significantly for Biocon this fiscal. The amount invested stood at approximately $14.6 million* (Rs 79 crore) for the first half of 2012-13, a 54 percent increase over the same period last fiscal. "This reflects the progress made by our various biosimilars and novel molecule programs in the clinic, including a European phase III trial for rh-Insulin which has generated positive interim data," said Dr Kiran Mazumdar-Shaw, chairman and managing director of Biocon. " Whilst this has muted profitability, research and development remains a key investment to drive exponential growth in the future."

Biocon posted close to five percent year-on-year (YoY) jump in net profit in the second quarter of fiscal 2012-13. Dr Mazumdar-Shaw commented that the company has delivered good performance across verticals this fiscal (2012-13). "At the half year, we have seen a 23 percent YoY increase in revenues attributable to both volume growth as well as better export realization on account of a depreciating rupee. APIs and biosimilar insulins have seen significant business expansion in the emerging markets. Branded formulations and research services continue to deliver strong growth," she said.

The multi-center, randomized study of the recombinant human insulin was conducted in nearly 300 patients to compare efficacy, safety and immunogenicity of Insugen R(R)) and Isophane human Insulin (Insugen N(R)) against the innovator products (Actrapid(R) and Insulatard(R)) 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 II of the study to demonstrate additional safety and immunogenicity over one year is on and is expected to be

completed by next year with the final results expected in first half of fiscal 2013-14.

Commenting on these results, Ms Mazumdar-Shaw said, "The positive outcome of this global phase III study is a significant milestone in our global insulin 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(R)) demonstrate our commitment to pursue our global insulins strategy and deliver affordable therapy to the patients."

"This was our first global study for rh-Insulin and we are pleased with the outcome," said Dr Abhijit Barve, President Research and Development of Biocon. "These data and our recent positive PK-PD data for Biosimilar Glargine enable us to pursue our global development strategy for Biosimilar Insulins."

In another development, GE Capital has agreed to invest in Syngene. GE Capital will invest approximately $23 million* (Rs 125 crore) for a 7.69 percent equity share in the Biocon subsidiary.

**Dollar conversion according to current rate*