



## **Biocon announces preliminary data on its novel oral insulin drug candidate.**

### **Top line data show encouraging results in patients with Type 2 Diabetes.**

***Bangalore, January 10<sup>th</sup> 2011***

Biocon, Asia's leading biopharmaceutical enterprise, released preliminary data from a recently concluded clinical study conducted in India, on IN-105, its novel oral insulin candidate for the treatment of diabetes.

A total of 264 patients were enrolled at multiple centers across India, in the double-blind placebo controlled trial. Patients poorly controlled on metformin were randomized to receive either IN-105 or placebo. The patients in both arms of the study were allowed to continue on metformin as background therapy.

Initial data analyses show that IN-105 did not meet its primary end point of lowering HbA1c levels by 0.7% compared to placebo although an unexpectedly high placebo response was also observed. Post hoc analysis of self monitored blood glucose levels in the IN-105 arm and the placebo arm indicated large reductions in pre-meal glucose levels in the placebo arm strongly suggestive of behavioural modification, and which might have confounded the primary endpoint outcome. Additionally, in further post hoc analyses, significant reductions in HbA1c levels compared to placebo, and HbA1c reductions of up to 0.8% were observed in the IN-105 arm of several subsets of the studied patient population. Further assessment of the data is on-going.

Multiple secondary endpoints on both efficacy and safety were met, further strengthening the emerging profile of IN-105. Most notably on efficacy, the IN-105 patient arm demonstrated a statistically significant reduction in post prandial glucose levels compared to placebo throughout the duration of the study.

Kiran Mazumdar-Shaw, MD and Chairman of Biocon said: "Based on these encouraging results, Biocon is committed to continue its global development of IN-105 in partnership with a global pharmaceutical partner for which we plan to initiate partnering discussions."

On secondary safety endpoints IN-105 demonstrated an excellent overall safety profile with no incidence of serious adverse events, and no occurrences of clinical hypoglycaemia. Data also show that the drug is weight neutral and non immunogenic.

Dr. Harish Iyer, Vice President, Research and Development at Biocon said: "These results build on the now considerable body of data generated for IN-105 strengthening our conviction of the promise of oral insulin. The lessons learned here will be fully utilized in designing future studies for the global clinical development program."



## **About Biocon Limited**

Established in 1978, Biocon Limited (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest biotechnology company by revenue. The Group, promoted by Ms Kiran Mazumdar-Shaw, is a fully-integrated, innovation-driven healthcare enterprise with strategic focus on biopharmaceuticals and research services. Biocon's value chain traverses the entire length of discovery, development and commercialization of novel therapeutics. With successful initiatives in clinical development, bio-processing and global marketing, Biocon delivers products and solutions to partners and customers in approximately 75 countries across the globe. Many of these products have USFDA and EMEA acceptance.