Press Release

Biocon Announces Data from Key Studies for Insulin Tregopil

Positive clinical data sets the stage for further development by Biocon

Bengaluru, India: Jan 21, 2016

Biocon Ltd, Asia's premier biotechnology company, today announced key data on Insulin Tregopil (formerly referred to as IN-105) following Phase 1 studies that validate and provide the basis for the next phase of clinical development of this important molecule. The clinical studies on Insulin Tregopil, which were conducted in the US under a US IND, were initiated in partnership with Bristol-Myers Squibb (BMS) prior to their divestment of the diabetes franchise to AstraZeneca.

Following are the key research outcomes of the Phase 1 study conducted in the US:

1. A major technological achievement was the development of a unique and specific assay for measuring Insulin Tregopil. This assay accurately differentiates between endogenous insulin and Insulin Tregopil in human plasma and thereby enables the assessment of pharmacokinetic effects of Insulin Tregopil.
2. A drug-drug interaction study of Insulin Tregopil and metformin shows that metformin does not affect the efficacy of Insulin Tregopil.
3. Food effect studies using the specific assay for Insulin Tregopil showed that high carbohydrate, high protein and high fat diets do not affect the efficacy of Insulin Tregopil.
4. Dosing studies conducted with meals show that there is a clear linear relationship between the dose of administered Insulin Tregopil and the decrease in postprandial glucose excursion rates.
5. Comparing orally administered Insulin Tregopil to injected Insulin Aspart shows that the effect of Insulin Tregopil occurs considerably more rapidly than Insulin Aspart, and is significantly shorter in duration of action than Insulin Aspart Consequently, Insulin Tregopil has the potential for more rapid insulinization of the liver and a significantly lower propensity to cause postprandial hypoglycemia than Insulin Aspart.

Commenting on the data, Dr Narendra Chirmule, Sr Vice President & Head of R&D at Biocon, said: "*These studies show that the oral delivery of insulin is feasible. It provides a novel opportunity for effective postprandial control of glucose metabolism through the physiological route of the portal system. In addition, because it can be used in early diabetes, this approach holds the potential to protect beta cells and may thereby delay disease progression."*

Ms. Kiran Mazumdar-Shaw, CMD, Biocon added: *"We are grateful to BMS for their partnership in the early development of this unique program. The data is extremely promising and based on what we know today Tregopil may be positioned as a unique oral Insulin. Confirmation of these findings in the next phase of clinical studies will set the stage for a paradigm shift in the treatment of Diabetes. This is an exciting moment for Biocon and hopefully for patients around the world. We have assembled a world renowned group of endocrinologists and diabetologists to work with us to drive the development of this molecule in the clinic."*

Dr. Harold Lebovitz, distinguished diabetes expert and member of Biocon's Clinical Advisory Board, said: *"Insulin Tregopil has the potential to finally provide the medical community with a true physiological treatment for postprandial hyperglycemia. Orally administered, a short while prior to meals, Insulin Tregopil is rapidly absorbed and reaches the liver within minutes through the normal physiologic route, the portal vein. The absorption of Insulin Tregopil is over within 60 to 90 minutes so that clinically significant postprandial hypoglycemia is negligible. Insulin Tregopil provides insulin treatment that primarily targets the liver without causing excessive peripheral hyperinsulinemia and this simulates normal insulin action. The two major complications of current insulin treatments, hypoglycemia and weight gain, could be potentially minimized by treatment with Insulin Tregopil."*

Prof. Alan Cherrington, preeminent laboratory investigator, who has carried out key pre-clinical research for IN-105 in dog models at Vanderbilt University, added: *"It is becoming increasingly clear that a normal distribution of insulin between the liver and fat (3:1) is of therapeutic advantage. Oral delivery of insulin represents one way to accomplish that. Thus the results of the recent human trials with Insulin Tregopil are very encouraging."*

Dr. Alexander Fleming, former senior endocrinologist at FDA, commented: *"I have been thankful for the opportunity to participate from near the beginning in this, the earliest ongoing, oral insulin program. It has been inspiring to witness the many challenges that have been tenaciously overcome by my colleagues at Biocon. I am glad to see Tregopil maintain its lead towards satisfying the very important need for an oral insulin product."*

Based on the above positive data sets, Biocon has decided to take this research asset into the next phase of clinical trials for validation in a larger patient cohort.

About Biocon Ltd:

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and fully-integrated, innovation-led biopharmaceutical company. As an emerging global biopharmaceutical enterprise serving customers in over 100 countries, it is committed to reduce therapy costs of chronic diseases like autoimmune, diabetes, and cancer. Through innovative products and research services it is enabling access to affordable healthcare for patients, partners and healthcare systems across the globe. It has successfully developed and taken a range of novel biologics, Biosimilars, differentiated small molecules and affordable recombinant human insulin and analogs from 'Lab to Market'. Some of its key brands are INSUGEN®(rh-insulin), BASALOG® (Glargine), CANMAb™ (Trastuzumab), BIOMAb-EGFR™ (Nimotuzumab) and ALZUMAb ™(Itolizumab), a 'first in class' anti-CD6 monoclonal antibody. It has a rich pipeline of Biosimilars and novel biologics at various stages of development including Insulin Tregopil, a high potential oral insulin analog.

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