

Press Release

## JDRF Supports Biocon Study of Novel, Fast-acting Oral Insulin Tregopil for Type 1 Diabetes Treatment

**Bengaluru, India, and New York, US, Sep 6, 2017:**

**Biocon Ltd. (BSE code: 532523, NSE: BIOCON)**, Asia's premier biopharmaceuticals company, and **JDRF**, the leading global organization funding type 1 diabetes (T1D) research and advocacy worldwide, jointly announced a JDRF partnership to support a global multiple ascending dose study with a novel oral insulin drug candidate, **Insulin Tregopil**, in people with T1D.

Insulin Tregopil, a first-in-class oral insulin molecule being developed by Biocon, is one of the most advanced programs in the global oral insulin space. The fast-acting oral insulin could improve post-prandial glucose control with reduced side effects and greater adherence, thus holding the promise to transform T1D management.

Biocon proposes to conduct an open label study to evaluate the pharmacokinetics (PK), pharmacodynamics (PD), safety and tolerability of multiple ascending doses of Insulin Tregopil and to compare the PK, PD and safety of the optimal dose regimen of Insulin Tregopil with therapeutic doses of Insulin Aspart in individuals with T1D.

This collaboration with Biocon is a part of JDRF's Industry Discovery and Development Partnership (IDDP) program, through which JDRF provides financial support to accelerate breakthrough research in T1D management.

Commenting on the collaboration, **Kiran Mazumdar-Shaw, CMD, Biocon** said, *"We believe Insulin Tregopil can make a significant difference to the diabetes management paradigm for both type 1 and type 2 diabetes and welcome JDRF's support in advancing this unique oral insulin molecule through the clinic for type 1 diabetes. With this proposed clinical study, we hope to build on the extremely promising data that we have generated so far through previous human trials with Tregopil. We are committed to addressing the huge unmet need of people with diabetes by providing the medical community an alternate treatment for postprandial hyperglycaemia."*

*"JDRF has been supportive of oral insulin studies to help people with type 1 diabetes better manage their glucose levels with less need for injected insulin," said **Esther Latres, JDRF Director, Translational Development**, "To achieve that goal would be one incredible step toward improving the quality of life for people with T1D while we strive for our ultimate goal of a cure."*

**Dr Narendra Chirmule, Sr. Vice President & Head of R&D at Biocon**, added, *"We are thankful to JDRF for extending their support to our R&D efforts that are aimed at developing a novel oral insulin to treat type 1 diabetes. The primary objective of this study will be to evaluate the safety and tolerability of*

*multiple ascending doses of Insulin Tregopil in individuals with type 1 diabetes. We are excited to work on this novel molecule and to partner with the world's leading organization supporting T1D research, JDRF."*

Globally, an estimated 422 million adults were living with diabetes in 2014<sup>1</sup>. While separate global estimates of diabetes prevalence for type 1 and type 2 do not exist, it is estimated that 1.25 million Americans are living with T1D<sup>2</sup>. Five million people in the U.S. are expected to have T1D by 2050<sup>3</sup>.

Biocon had announced positive clinical data in 2016 for Insulin Tregopil following a set of Phase I studies conducted in the U.S., which established the drug's important role in postprandial glycaemic control. One of the studies demonstrated fast action of Insulin Tregopil with distinctive properties compared to other prandial insulins. Based on the positive data sets, Biocon has decided to advance this research asset through clinical trials for validation in a larger patient cohort. The company has also filed a Clinical Trial Application with the Indian regulator (DCGI) for a Phase II/III study with Insulin Tregopil in type 2 diabetes.

### **About the Study**

The study is planned to be conducted in two parts. Part 1 of the study aims to derive the optimal dose and regimen of Insulin Tregopil in adults with T1D. Part 2 of the study aims to compare the PK-PD and tolerability of optimal dose regimen of Insulin Tregopil with Insulin Aspart when administered with various types of meals under standardized and real life scenarios. Approximately 70 T1D individuals will be enrolled in the study, which will be carried out at multiple centers in Europe.

### **ABOUT JDRF**

[JDRF](http://jdrf.org) is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested more than \$2 billion in research funding since our inception. We are an organization built on a grassroots model of people connecting in their local communities, collaborating regionally for efficiency and broader fundraising impact, and uniting on a national stage to pool resources, passion, and energy. We collaborate with academic institutions, policymakers, and corporate and industry partners to develop and deliver a pipeline of innovative therapies to people living with T1D. Our staff and volunteers throughout the United States and our six international affiliates are dedicated to advocacy, community engagement and our vision of a world without T1D.

***For more information, please visit [jdrf.org](http://jdrf.org) or follow us on Twitter: @JDRF.***

### **About Biocon**

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 diabetes, cancer and autoimmune. 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

Analog from 'Lab to Market'. Some of its key brands are INSUGEN® (rh-insulin), BASALOG® (Insulin 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.

**For more information please visit [www.biocon.com](http://www.biocon.com) or follow us on Twitter @bioconlimited**

**About Type 1 Diabetes**

Type 1 diabetes (T1D) is an autoimmune disease in which a person’s pancreas stops producing insulin, a hormone that enables people to get energy from food. It occurs when the body’s immune system attacks and destroys the insulin-producing cells in the pancreas, called beta cells. While its causes are not yet entirely understood, scientists believe that both genetic factors and environmental triggers are involved. Its onset has nothing to do with diet or lifestyle. There is nothing you can do to prevent T1D, and — at present — nothing you can do to get rid of it.

Sources:

1. Global report on diabetes, WHO; 2016
2. CDC National Diabetes Statistics Report, 2014
3. JDRF Website

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