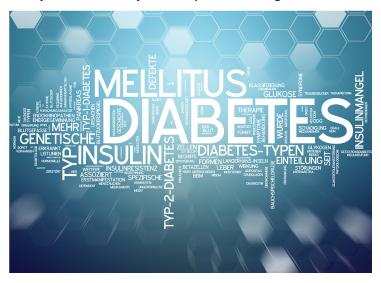


JDRF joins Biocon for global diabetes study

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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.



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. 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. Five million people in the U.S. are expected to have T1D by 2050.

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.