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Sanofi declares results of Lantus clinical trial

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Bangalore: The results of the landmark ORIGIN (Outcome Reduction with Initial Glargine Intervention) trial showed that Lantus, Sanofi's brand of insulin glargine [rDNA] injection, had no statistically significant positive or negative impact on cardiovascular outcomes versus standard care, during the study period. sanofi said results from the trial also showed that insulin glargine delayed progression from pre-diabetes to type 2 diabetes and there was no association between insulin glargine use and increased risk of any cancer. The study findings were presented at the American Diabetes Association 72nd Scientific Sessions and also published online in the New England Journal of Medicine.

ORIGIN, the world's largest diabetes clinical trial, was a six-year randomized clinical trial designed to assess the effects of treatment with insulin glargine versus standard care on Cardiovascular (CV) outcomes. The study involved over 12,500 participants worldwide with pre-diabetes or early type 2 diabetes mellitus and high CV risk, with 6,264 participants randomized to receive insulin glargine titrated to achieve fasting normoglycemia. The co-primary endpoints were the composite of CV death, or non-fatal myocardial infarction, or non-fatal stroke; and the composite of CV death, or non-fatal myocardial infarction, or non-fatal stroke, or revascularization procedure, or hospitalization for heart failure.

"We now know more about insulin glargine than about any other glucose lowering drug with respect to future health outcomes," commented Dr. Hertzel Gerstein, McMaster University and Principal Investigator of the ORIGIN trial. "Specifically, it maintains excellent glycemic control, slows progression of dysglycemia and has no long-term serious health effects. Moreover, this academically led and analyzed trial is an excellent example of collaboration between industry and academia."

Dr Ramachandran, President- India Diabetes Research Foundation, and National Coordinator of the ORIGIN trial for India and co-author of the ORIGIN primary papers, said, "The rich data and findings of ORIGIN have provided us insights into many hitherto unanswered questions in diabetes management, and have also reinforced our confidence on the use of Lantus as a reference basal insulin with long-term proven efficacy and established safety."

Dr Mohan Badgandi, Consultant in diabetes, endocrinology, obesity and metabolic medicine, Manipal Hospital, Bangalore further reiterated the importance of this trial when he said, "Over the past decade there has been an alarming rise in the

number of diabetics in India, with many being unaware that they have the disease. Given the social and economic impact of diabetes, it is important to make concentrated efforts to help create awareness about diagnosis, management and treatment of diabetes.

ORIGIN is a step in this direction. It brings to light the possibility of preventing complications in diabetic patients through early insulin therapy."

"In patients with pre-diabetes or early type 2 diabetes and high CV risk, ORIGIN shows that it is possible to maintain low and stable HbA1c levels that are close to normal over a long time, and to potentially delay the progression from pre-diabetes to diabetes. Sanofi is proud to have sponsored this trial as a vital contribution to improving understanding of diabetes and the impact of long-term glycemic control," commented Riccardo Perfetti, MD, Vice President Medical Affairs, Global Diabetes, Sanofi.

"Our commitment to funding this vitally important long-term trial exemplifies our aim to help identify new ways of treating and understanding diabetes," commented Pierre Chancel, Senior Vice President, Global Diabetes, Sanofi. "I am pleased to announce that Sanofi will extend the observations of ORIGIN by an additional two years. All of these data will build on the extensive Lantus evidence in more than 47 million real-life patient-years and over 10 years of clinical experience involving 80,000 participants in clinical development programs."