ORIGIN Results on Lantus® Cardiovascular Safety Integrated Into European Union Product Label

Paris, France - June 5, 2013 - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for inclusion in the Lantus® (insulin glargine) product label of safety and efficacy data from the insulin glargine cardiovascular (CV) outcomes trial ORIGIN (Outcome Reduction with Initial Glargine INtervention). The revised label is evidence of Sanofi's ongoing commitment to further assert the well-known safety and efficacy profile of insulin glargine, the most-studied basal insulin. The indication for the use of Lantus® remains unchanged.

ORIGIN was a landmark, seven-year clinical trial that randomized over 12,500 participants at high CV risk with impaired fasting glucose, impaired glucose tolerance or early type 2 diabetes mellitus to a once-daily injection of Lantus® versus standard care of their hyperglycemia (treatment limited to none or at most one oral antidiabetic agent).

Results from the ORIGIN trial included in the product label are as follows: Insulin glargine did not alter the relative risk for CV disease and CV mortality when compared to standard of care. ORIGIN showed no differences between insulin glargine and standard care treatment regarding the co-primary endpoints of the composite of time to first occurrence of CV death, non-fatal myocardial infarction, or non-fatal stroke (hazard ratio [HR]: 1.02; p=0.63, NS); and the composite of CV death, or non-fatal myocardial infarction, or non-fatal stroke, or revascularization procedure, or hospitalization for heart failure (HR: 1.04; p=0.27, NS).

The rates of severe hypoglycemia (affected participants per 100 participant years of exposure) were 1.05 and 0.30 for insulin glargine and standard care groups, respectively. Rates of confirmed non-severe hypoglycemic events were 7.71 for insulin glargine and 2.44 for standard care groups. Over the course of this seven-year study, 42% of the insulin glargine group did not experience any hypoglycemia.

"*The addition of the ORIGIN results to the Lantus® label is particularly important in the current context of the increasing debate on cardiovascular safety of diabetes treatments, and it reinforces the proven efficacy and safety profiles of Lantus®,"* commented Pierre Chancel, Senior Vice President, Global Diabetes, Sanofi. *"Lantus® has helped millions of people manage their diabetes for over a decade, resulting in trust and reassurance, which is key to successful disease management."*

ORIGIN was academically led and analyzed by a team of diabetes and cardiovascular disease experts with sponsorship from Sanofi.

About ORIGIN

ORIGIN (Outcome Reduction with Initial Glargine Intervention) is a unique, seven-year landmark cardiovascular (CV) outcomes trial, evaluating Lantus® (insulin glargine) versus standard care in over 12,500 individuals who are at high CV risk with pre-diabetes or early type 2 diabetes mellitus. Spanning 40 countries worldwide, it is the world's longest and largest randomized clinical trial of its type in this population, and the first to formally evaluate the effects of insulin glargine on CV outcomes. The trial used a 2x2 factorial design to determine whether using insulin glargine to target fasting normoglycemia (FPG ≤ 95mg/dL) compared to standard glycemic management, and separately omega-3 polyunsaturated fatty acids (PUFA) vs placebo, could reduce cardiovascular morbidity and/or mortality.[1] Participants assigned to standard care were treated on the basis of the investigator's best judgment and local guidelines, including lifestyle measures, dietary modifications, and non-glargine anti-diabetic agents.

There were no differences found between insulin glargine and standard care for the other secondary outcomes which included a composite microvascular outcome (metrics of kidney or eye disease; [HR: 0.97; p=0.43]), and all-cause mortality (HR: 0.98; p=0.70). Insulin glargine achieved targeted long-term glycemic control (median fasting plasma glucose 5.2 mmol/L and HbA_{1C} 6.2%), which was sustained over the mean of 6.2 years of follow-up. At the end of the trial, there was modest mean increase in body weight from baseline of 1.4 kg in the insulin glargine group and a mean decrease of 0.8 kg in the standard care group.

About Diabetes

Diabetes is a chronic disease that occurs as type 1 diabetes, which is an autoimmune disease characterized by the lack of insulin (the hormone that regulates blood glucose concentrations) production by the pancreas, and type 2, a metabolic disorder in which there are two main biological defects: a deficient production of insulin and reduced ability of the body to respond to the insulin being produced. Type 1 and type 2 diabetes are characterized by an increase in blood glucose concentrations (hyperglycemia). Over time, uncontrolled hyperglycemia leads to the macrovascular and microvascular complications of diabetes. Macrovascular complications, which affect the large blood vessels, include heart attack, stroke and peripheral vascular disease. Microvascular complications affect the small blood vessels of the eyes (retinopathy), kidney (nephropathy) and nerves (neuropathy). The global incidence of diabetes is growing at an alarming rate, with more than 371 million people worldwide living with the condition today.[2]

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services and devices, including blood glucose monitoring systems. Sanofi markets both injectable and oral medications for people with type 1 or type 2 diabetes.

About Sanofi

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

References

1. ORIGIN Trial Investigators, Gerstein H, Yusuf S, et al. Rationale, design, and baseline characteristics for a large international trial of cardiovascular disease prevention in people with dysglycemia: the ORIGIN Trial (Outcome Reduction with an Initial Glargine Intervention). *Am Heart J* 2008; **155**(1): 26-32.
2. International Diabetes Federation. *IDF Diabetes Atlas, 5th edition.* Brussels, Belgium, 2011. http://www.idf.org/diabetesatlas (Accessed: February 14, 2013)

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