Sanofi Announces Results of ORIGIN, the World's Longest and Largest Randomized Clinical Trial in Pre- and Early Diabetes

Paris, France – June 11, 2012 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today results from the landmark ORIGIN trial (Outcome Reduction with Initial Glargine Intervention), which showed that Lantus® (insulin glargine [rDNA] injection) had no statistically significant positive or negative impact on cardiovascular (CV) outcomes versus standard care during the study period. Results 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 today at the American Diabetes Association 72nd Scientific Sessions and also published online in the *New England Journal of Medicine* (NEJM).

ORIGIN was a six-year randomized clinical trial designed to assess the effects of treatment with insulin glargine versus standard care on 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, Hamilton, Ontario/Canada 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*."

The study demonstrated that achieving fasting normoglycemia did not affect CV outcomes in these participants with early dysglycemia during the study period (first co-primary endpoint: Hazard Ratio [HR]: 1.02; p = 0.63, NS; and second co-primary endpoint: HR: 1.04; p = 0.27, NS).

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 6.2 years of follow-up.

There was no association between insulin glargine and increased risk of any cancer (HR: 1.00; p = 0.97, NS). Neither analysis of all cancers combined, nor analysis of any organ-specific type of cancer, suggested an increased risk for the users of insulin glargine.

Results showed that insulin glargine delayed progression from pre-diabetes (IFG or IGT) to type 2 diabetes mellitus by 28% (HR: 0.72; p = 0.006). Other secondary outcomes 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).

"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 HbA_{1c} 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.

Hypoglycemic events were infrequent. In the insulin glargine arm, the rate of severe hypoglycemia was 0.01 episodes per patient-year of exposure versus 0.003 episodes per patient-year for standard care. Rates for overall hypoglycemia with insulin glargine were 16.7 patients with events per 100 patient-years of exposure versus 5.2 patients with events per 100 patient-years for standard care. In addition, weight gain was modest for participants in the insulin glargine arm, at an average of 3.5 pounds over the duration of the study.

ORIGIN investigated the use of insulin glargine in a population in which insulins are not typically used,[1] providing new data on the potential benefits and risks of initiation of insulin glargine therapy earlier in the course of diabetes (average disease duration since diagnosis at entry in trial: 5.8 years).

"*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[2] and over 10 years of clinical experience involving 80,000 participants in clinical development programs."*

The extension of the observations of ORIGIN will be called ORIGINALE (Outcome Reduction with an Initial Glargine Intervention and Legacy Effect).

About ORIGIN

ORIGIN (Outcome Reduction with Initial Glargine Intervention) is a unique, six-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 on CV outcomes. The trial used a 2x2 factorial design to determine whether using insulin glargine to target fasting normoglycemia (FPG ≤ 95mg/dL), and separately omega-3 polyunsaturated fatty acids (PUFA), could reduce cardiovascular morbidity and/or mortality[3]. Participants assigned to standard care were treated on the basis of the investigator's best judgment and local guidelines, including lifestyle measures, dietary modifications, metformin, sulfonylureas and other oral anti-diabetic agents.

About Diabetes

Diabetes is a long-term disease that occurs either when the pancreas does not produce enough insulin (the hormone that regulates blood glucose concentrations), or when the body cannot effectively use the insulin it produces, or both. This results in raised blood glucose concentrations (hyperglycemia). Over time, uncontrolled hyperglycemia leads to the macrovascular and microvascular complications of diabetes.[4] 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 incidence of type 2 diabetes is growing at an alarming rate, with over 310 million people worldwide living with the condition today.[5]

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 innovative blood glucose monitoring systems. Sanofi markets both injectable and oral medications for people with type 1 or type 2 diabetes. Investigational compounds in the pipeline include an injectable GLP-1 agonist being studied as a single agent, in combination with basal insulin, and/or in combination with oral antidiabetic agents.

To view the Sanofi ADA electronic press packet, please go to www.epresspack2.net/Sanofi-at-ADA/

About Sanofi

Sanofi, a global and diversified 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. Lantus® is indicated for treatment of diabetes mellitus when insulin is required.
2. Periodic safety report, April 2012
3. 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.
4. UK Prospective Diabetes Study (UKPDS) Group, Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33), Lancet 1998;352(9131):837-853
5. World Health Organisation diabetes fact sheet, August 2011

Sanofi Forward Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Sanofi will host a conference call for the financial community during the upcoming American Diabetes Association Annual Meeting, including the results of the ORIGIN landmark study and two retrospective cohort studies on Lantus® (insulin glargine).

It will take place on **Tuesday June 12th, 2012** at**: 12:30PM Paris CEST / 11:30AM London BST/ 6:30AM New York EDT.**

The conference call will include a presentation followed by a Q&A session. It will be accessible through audio webcast at www.sanofi.com and via the following telephone numbers.

CALL IN NUMBERS

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USA	+1 866 907 5925

AUDIO REPLAY

An audio replay of the call will be available through the numbers below. The replay will be available approximately 2 hours after the end of the call.

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