Lantus® Initiation after Metformin Achieved Superior Glycemic Control versus Sitagliptin in Type 2 Diabetes

– Approximately 50 percent more patients on Lantus® achieved target HbA_{1c} versus sitagliptin at study endpoint –

– EASIE study findings published in The Lancet –

Paris, France – June 9, 2012 – Sanofi (EURONEXT : SAN and NYSE : SNY) announced today that people with early type 2 diabetes uncontrolled on metformin demonstrated superior HbA_{1c} - glycated hemoglobin - reduction with Lantus® (insulin glargine [rDNA origin] injection) versus sitagliptin. These data from the EASIE (**E**valuation of Insulin Gl**a**rgine Versus **S**itagliptin in **I**nsulin-Naïv**e** Patients) study were presented at the American Diabetes Association 72nd Scientific Sessions. Results of the study were also published today online in *The Lancet*.

"*The findings of this study comparing insulin glargine with sitagliptin provide evidence to support the recent ADA-EASD proposal to consider early basal insulin therapy as add-on to metformin to help achieve glycemic control in people with type 2 diabetes,"* said principal investigator Pablo Aschner, Pontificia Universidad Javeriana, Hospital Universitario San Ignacio, Colombia.

In insulin-naïve people with type 2 diabetes, who were inadequately controlled by metformin once-daily, insulin glargine produced superior HbA_{1c} reduction (-1.7%) versus once daily sitagliptin (-1.1%; p<0.001). Notably 50% more patients on insulin glargine achieved HbA_{1c}<7% (68 vs. 42%) and <6.5% (40 vs. 17%) compared to sitagliptin (p<0.0001 for both), indicating improved glycemic control for a greater number of insulin glargine patients. Additionally, a statistically significant improvement in fasting plasma glucose (FPG), a key contributor to glycemic control, was observed for patients on insulin glargine compared to sitagliptin. The mean difference in self-monitored FPG was -41.4 mg/dL (95% CI: -46.8 to -36.0 mg/dL) lower with insulin glargine than with sitagliptin (p<0.0001).

Treatment-emergent adverse events were less frequent in patients on insulin glargine (108 patients [46%]) versus sitagliptin (143 patients [54%]). Hypoglycemia rates were higher with insulin glargine (4.21 events per patient year versus 0.50 for sitagliptin; p<0.0001). The number of patients with overall symptomatic hypoglycemia and nocturnal symptomatic hypoglycemia, with plasma glucose (PG) < 56 mg/dL, was 56 with insulin glargine compared to 12 with sitagliptin, and 20 vs. 2, respectively. Severe symptomatic hypoglycemia was reported in 3 patients receiving insulin glargine compared to 1 receiving sitagliptin. Severe nocturnal symptomatic hypoglycemia was reported in 1 patient in each group. Mean body weight slightly increased with glargine (+0.4 kg) and decreased with sitagliptin (-1.1 kg).

"The EASIE study adds valuable data to further strengthen the efficacy profile of Lantus® when initiated early in the treatment pathway after metformin," said Pierre Chancel, Senior Vice President, Global Diabetes, Sanofi. "EASIE is a demonstration of the continued commitment of Sanofi to helping people with type 2 diabetes reach their glycemic targets."

The study findings are highlighted at the American Diabetes Association Scientific Sessions in the following abstract: **Evaluation of Insulin Glargine Versus Sitagliptin in Insulin-Naïve Patients (EASIE) With Type 2 Diabetes Mellitus (T2DM) Uncontrolled in Metformin (Aschner et al.)** [CT-SY22].

About EASIE

EASIE was a multicenter, international, randomized, open-label, six-month study that compared once-daily insulin glargine with sitagliptin (100 mg) once daily, as add-on therapy to metformin, in insulin-naïve people with early type 2 diabetes (median disease duration after diagnosis: 4.5 years). The primary endpoint was to demonstrate superiority of insulin glargine (n = 227 at study end) over sitagliptin (n = 253 at study end) in change in HbA_{1c} from baseline to study end. Baseline characteristics were similar for both groups.

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.[1] 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.[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 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. World Health Organisation diabetes fact sheet, August 2011
2. 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

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 labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product 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, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding 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.

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