New Epidemiological Data Provide Additional Safety Evidence for Lantus®

– No increased risk of cancer found with Lantus® in new European and U.S. observational studies –

Paris, France – June 11, 2012 - Sanofi (EURONEXT: SAN and NYSE: SNY) today announced new results of a large-scale epidemiological program, conducted by independent researchers in the northern European countries, at Kaiser Permanente in Northern and Southern California, and at the University of North Carolina in the United States, providing further evidence that there was no increased risk of cancer in people with diabetes treated with Lantus® (insulin glargine [rDNA origin] injection), compared to those treated with other insulins. These data were presented at the American Diabetes Association 72nd Scientific Sessions.

Aiming to evaluate cancer risk in diabetes and generate comprehensive insulin glargine exposure data from large databases, the epidemiological program sponsored by Sanofi is the largest observational program designed for this purpose to date.

These new results reinforce the established safety profile of Lantus®, complementing the existing wealth of data already available[1] resulting from more than 80,000 patients enrolled in clinical trials and over 47 million patient-years[2] of treatment exposure to insulin glargine.

"Sanofi welcomes the results of the Northern European and United States epidemiological studies further supporting the safety of Lantus®," said Jean-Pierre Lehner, Senior Vice President, Chief Medical Officer, Sanofi. *"These findings reassure healthcare professionals, people living with diabetes and their caregivers of the safety profile of Lantus®."*

Northern European Database Study [American Diabetes Association 72nd Scientific Sessions Symposium CT-SY13]

This study is the largest of its kind with 447,821 patients using insulin and over 1.5 million person-years of observation. The average follow-up time is 3.1 years for patients on glargine and 3.5 years for those on other insulins. In answering the primary hypothesis, among all users of insulin, and similarly among users of human insulin, this observational study found no evidence of an increased risk of breast cancer in women (HR: 1.12; 95% CI: 0.99-1.27), prostate cancer in men (HR: 1.11; 95% CI: 1.00-1.24) and colorectal cancer in men and women (HR: 0.86, 95% CI: 0.76-0.98) in users of insulin glargine vs. other insulins.

Furthermore, there was no evidence of an increased risk in users of insulin glargine vs. other insulins relative to the pre-specified secondary hypothesis (risk of all forms of cancer combined) and the exploratory hypothesis (risk of lung or pancreatic cancer).

In conclusion, the results showed no increased risk for cancer in association with the use of insulin glargine compared to users of other insulins.

Lead investigator Peter Boyle, PhD, President of the International Prevention Research Institute (iPRI), Lyon, France, stated: "*These findings provide further evidence that insulin glargine does not*

increase the risk of cancer. The results of this study are reassuring from a patient and physician perspective."

The Northern European Study was carried out in five countries: Denmark, Finland, Norway, Sweden and Scotland. The Committee for Medicinal Products for Human Use (CHMP) in Europe expressed that the Northern European study results add important knowledge for understanding on the safety of Lantus®.

Results from Kaiser-Permanente Collaboration [American Diabetes Association 72nd Scientific Sessions Symposium CT-SY13]

The main analyses of this U.S. database study (using the Northern and Southern California Kaiser Permanente diabetes registries included 115,000 patients with median duration of 1.2 years for glargine use and 1.4 years for neutral protamine Hagedorn (NPH) among all insulin users (Lantus® and NPH insulin) showed no association between use of insulin glargine and increased risk of breast cancer (HR: 1.0; 95% CI: 0.9-1.3), prostate cancer (HR: 0.7; 95% CI: 0.6-0.9) or colorectal cancer (HR: 1.0; 95% CI: 0.8-1.2) (primary endpoints). Furthermore, there was no association between Lantus® use and increased risk of all cancers combined (HR: 0.9; 95% CI: 0.9-1.0) (secondary endpoint).

In a sub-analysis using one specific methodology (counting of dose), there was a suggestion of a very modest increase of breast cancer in patients with two or more years of Lantus® use. When another methodology was adopted (counting of prescriptions), no such suggestion existed. Principal Investigator Laurel Habel, PhD, Research Scientist at the Kaiser Permanente Northern California Division of Research, noted that results of their study should be viewed cautiously, given the relatively short duration of glargine use, the low number of events, and the large number of associations examined.

The Northern European Database Study and the U.S. study using the Northern and Southern California Kaiser Permanente diabetes registries were endorsed by the European Medicines Agency (EMA).

Results from MedAssurant Database [American Diabetes Association 72nd Scientific Sessions Symposium CT-SY13]

The U.S. database study was complemented by findings from researchers at the University of North Carolina, using the healthcare database MedAssurant (43,306 patients on glargine and 9,147 on NPH; mean duration of treatment: 1.2 years for glargine group and 1.1 years for NPH group). There was no evidence of an increased risk for cancer, and specifically for breast cancer.

"This robust analysis of high quality data from the U.S. shows that there is no association with an increased risk of cancer in users of insulin glargine," concluded John Buse, MD, PhD, former President of the American Diabetes Association, and Director of the Diabetes Care Center at the University of North Carolina, USA, who led the U.S. database studies.

As with the results of the Northern European Study, data from the U.S. Kaiser Permanente and MedAssurant studies showed no association between use of Lantus® and increased risk of the cancers evaluated among all insulin users tested. Additional results are expected from a third observational study, the International Study of Insulin and Cancer (ISICA), which will be completed in 2012.

About the Epidemiology Program

Sanofi is sponsoring a large-scale, methodologically-robust epidemiology program, as agreed with EMA and shared with health authorities worldwide. The epidemiology program includes the Northern

European Epidemiological Study and two additional large studies, all conducted by independent investigators – the U.S. database study (Kaiser Permanente), conducted by John Buse, MD, PhD, former President of the American Diabetes Association, and Director of the Diabetes Care Center at the University of North Carolina School of Medicine; and the International Study of Insulin and Cancer (ISICA), which explores specifically breast cancer and is led by Lucien Abenhaim, Professor of Public Health at the University of Paris and former Director General for Health in France. ISICA is currently being conducted in France, UK and Canada and is due for completion in 2012.

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.[3] 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.[4]

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. Home P *et al.* Meta-analysis of 31 randomized clinical trials including a total number of 10,880 patients with Type 1 and Type 2 diabetes confirmed that Lantus® was not associated with an increased incidence of cancer compared with comparator, mainly NPH. *Diabetologia* 2009: 52(9):2499–2506
2. Safety Monitoring Report, April 2012
3. 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
4. World Health Organization 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 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.

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

France	+33 (0) 1 70 77 09 39
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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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