Two new meta-analyses confirm once-daily Lantus® efficacy and reduced risk of hypoglycaemia compared to NPH Insulin

Paris, France – September 30, 2009 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today results of a new analysis that found a significantly lower risk of nocturnal hypoglycaemia with Lantus® (insulin glargine [rDNA] injection) as compared to NPH insulin. A separate post-hoc sub-analysis found a greater HbA1c and FBG reduction for elderly patients over 65 years of age taking Lantus® as compared to NPH insulin. Both analyses were presented during the 45th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Vienna.

The first analysis[1] demonstrated that should they be treated with Lantus®, in around 6 months, 1 in 8 patients using Lantus® would avoid a confirmed symptomatic event compared to patients using NPH ($p<0.0001$). The analysis also found that there was a significantly lower risk of nocturnal hypoglycaemia with Lantus® treatment and that daytime symptomatic hypoglycaemia tended to be lower with Lantus® *vs*. NPH, but the differences were not statistically significant.

"The avoidance of confirmed symptomatic hypoglycemic events with Lantus® is highly meaningful for patients," said Professor Philip Home, Newcastle University, UK, author of the study. "*The studies also found that there was a significantly lower risk of nocturnal severe hypoglycaemia, which may help patients better adhere to their insulin therapy*."

Fear of hypoglycaemia can delay insulin initiation and prevent adequate blood glucose control. Nocturnal hypoglycaemia is particularly feared by healthcare professionals and patients because it often goes unrecognised. Left undetected, hypoglycaemia can lead to increased morbidity such as sleep disturbance, morning headache, chronic fatigue or mood changes.

A second meta-analysis[2] demonstrated a reduced risk of nocturnal hypoglycaemia with once-daily Lantus® patients over NPH. In particular, in elderly patients over 65, not only was there a reduced risk of nocturnal hypoglycemia (1.99 vs 3.45 events per patient year $p<0.0001$), but also a greater HbA1c reduction (1.2% v 0.9% $p<0.05$) was achieved with Lantus® over NPH insulin in a post-hoc analysis.

"Improved glycaemic control can reduce the risk of micro- and macrovascular disease. In older adults, diabetes treatment should be individualized for each patient to achieve optimal glucose control while avoiding adverse side effects," stated Dr. Pearl Lee, University of Michigan, U.S., author of the study. *"Physicians often fear hypoglycaemia in the elderly. Our study demonstrates that with Lantus® one can achieve both greater efficacy and a lower risk of hypoglycaemia in comparison to NPH."*

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About the meta-analyses

(1) Home, P et al: Estimating Number-Needed-to-Treat with Insulin Glargine (GLAR) Compared with NPH Insulin to Avoid a Hypoglycemic Episode in People with Type 2 Diabetes (T2D): a Meta-analysis.

Five studies conducted between 2000 and 2007 were included in the analysis of evening Lantus® injection (n=2711). Patients had a mean age of nearly 60 years, were moderately overweight (mean BMI 28.0–29.0 kg/m2) had a mean disease duration of 10 years, and were using a combination of insulin and oral glucose-lowering drugs. Most of the patients were insulin naïve. All of the patients were using a combination of insulin and oral agents.

The primary outcome was between-treatment comparison of the proportion of patients with ≥1 hypoglycaemic event differentiated into time of occurrence (daytime or nocturnal, and total events) adjusted for change in HbA1c from baseline to end of the study. Secondary endpoints were hypoglycaemic events by category/severity. The categories were severe, or symptomatic with self-monitoring blood plasma levels of <2.00 mmol/L (36 mg/dL) or <3.9 mmol/L (70 mg/dL). Severity of hypoglycaemia and the time of day of occurrence was documented for more than 97% of participants (Lantus® : n=1303, NPH: n=1338).

(2) Lee, P et al: Safety and Efficacy of Insulin Glargine compared with NPH Insulin in older adults with T2DM. EASD 2009: Pooled Analysis

Data were pooled from four similar, international, multisite, randomized clinical trials comparing the safety and efficacy of the addition of Lantus® or NPH insulin to uncontrolled OADs patients. All patients in these trials were insulin naive, had diagnosed type 2 diabetes, and were treated with a basal insulin only (Lantus® or NPH insulin). Duration of treatment in all studies was 24 weeks.

Studies were compared for HbA1c reduction and hypoglycemic events at the end of 24 weeks in patients ≤65 (Lantus® [n=831] versus NPH [n=859]) and >65 years (Lantus® [n=215] versus NPH [n=236]).

Authors found that the rate of nocturnal hypoglycaemia was statistically significantly lower with Lantus® than with NPH in both age groups studied (below 65 and above 65 years old): (1.1 versus 2.3 average events per patient year [p<0.0001] ; and 1.3 versus 2.7 average events per patient year [p<0.005] respectively). The number of symptomatic hypoglycemic events per patient year in these older patients was 2.2 for Lantus® and 2.4 for NPH, with 0.01 severe hypoglycemic events for Lantus® and 0.03 for NPH.

Among patients 65 or younger, there was no significant difference between Lantus® and NPH in HbA1c reduction (1.26% for Lantus®, 1.20% for NPH) or FBG reduction (86 mg/dL for Lantus®, 84 mg/dL for NPH) after 24 weeks of treatment. Similar results were also found for daytime symptomatic hypoglycemic events per patient year in patients ≤65 years old (2.4 for Lantus® and 2.6 for NPH) and severe hypoglycemic events (0.03 for Lantus® and 0.04 for NPH)

About Lantus® and Lantus® SoloSTAR®

Lantus® is indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia and for adult and pediatric patients (6 years and older) with type 1 diabetes mellitus. Lantus® demonstrates a peakless and sustained concentration/time profile over 24h thus reducing the risk of hypoglycemia and allowing a constant and high efficacy over 24h with one single daily injection. Lantus® is the number one prescribed insulin worldwide.

Lantus® should not be diluted or mixed with any other insulin or solution. The most common side effect of insulin, including Lantus®, is hypoglycemia, which may be serious. Other possible side effects may include injection site reactions, including changes in fat tissue at the injection site, and allergic reactions, including itching and rash. In rare cases, some allergic reactions may be life threatening.
Lantus®SoloSTAR® is an easy-to-use pen specifically designed for Lantus® and requires only few straightforward steps to be used properly. Lantus® SoloSTAR® eliminates the need for the patient to change cartridges.

About Diabetes

Diabetes is a chronic, widespread condition in which the body does not produce or properly use insulin, the hormone needed to transport glucose (sugar) from the blood into the cells of the body for energy. More than 230 million people worldwide are living with the disease and this number is expected to rise to a staggering 350 million within 20 years. It is estimated that nearly 24 million Americans have diabetes, including an estimated 5.7 million who remain undiagnosed. At the same time, about 40 percent of those diagnosed are not achieving the blood sugar control target of HbA1c <7 percent recommended by the ADA. The HbA1c test measures average blood glucose levels over the past two- to three-month period.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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 product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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-aventis' 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-aventis, 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 EMEA, 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 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 as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

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The sanofi-aventis diabetes press conference will take place on September 30th at 6:00 PM CET at the Vienna EASD Congress. You will be able to access this press conference through a webcast available via the following link:

http://proxy.web.dbee.com/sanofi/20090930/en/
password: sa2009EASD