Superior efficacy-dose ratio for Lantus® over detemir

- 76% higher dose of insulin detemir needed to achieve similar, well tolerated glycemic control versus Lantus® -

Paris, France – September 30, 2009 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today results of a head-to-head study providing further evidence on the efficacy of once-daily, 24-hour basal insulin Lantus® (insulin glargine [rDNA] injection) compared to twice-daily insulin detemir. The study was presented during the 45th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Vienna.

In the head-to-head, randomised, non-inferiority controlled clinical trial of 964 patients, patients taking Lantus® required an average daily dose of 43.5 units to achieve the primary endpoint of HbA_{1c} below 7% without symptomatic hypoglycaemia compared to patients on insulin detemir, who received 76.5 units - an increase of 76% ($p<0.001$). Despite lower doses of insulin in the glargine group, Lantus® once-daily and insulin detemir twice-daily resulted in similar improvements in glycemic control (HbA_{1c}) and a similar risk of hypoglycaemia (primary endpoint: 27.5% vs 25.6%, $p=0.52$). Patients in the Lantus® arm of the study also achieved significantly lower fasting blood glucose (-63.1 mg/dL Lantus® vs -57.7 mg/dL, $p<0.001$).

"This study demonstrated that for insulin-naïve patients with type 2 diabetes, initiating insulin therapy with once-daily glargine achieved the same glycemic control as twice-daily detemir, with somewhat more weight gain, but lower insulin doses", stated Study Investigator Hertzel Gerstein, Professor of Diabetes Medicine, Faculty of health sciences, Hamilton, Canada.

In the study, patients taking Lantus® once-daily reported a significantly greater treatment satisfaction over insulin detemir twice-daily, with over 50% less drop-outs (4.6% vs 10.1%, $p=0.001$). Discontinuations in patients taking insulin detemir were primarily due to adverse events, including skin reactions. Whilst a similar rate of overall hypoglycaemia and nocturnal hypoglycaemia was observed in both arms, patients on Lantus® once-daily experienced less daytime hypoglycaemia as compared to insulin detemir (1.06 vs 1.64 events per patient year, $p=0.046$). Patients on insulin detemir experienced less weight gain (0.6 vs 1.4 kg, difference 0.77 kg, $p<0.001$).

About the Lantus® *vs.* insulin detemir study[1]

In the study, a total of 964 insulin-naïve patients were examined. Patients were between 40 to 75 years of age and had type 2 diabetes for at least 1 year with sub-optimal blood glucose control using glucose-lowering drugs.

Patients were randomised and treated with Lantus® once daily, at either dinner or bedtime, or insulin detemir twice daily, both at breakfast and before dinner, along with stable doses of metformin.

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Thiazolidinedione treatment was halted as of insulin randomisation, but insulin secretagogues were continued or discontinued at the investigator's discretion.

For both insulins, the starting daily dose was 0.2 U/kg, which was then titrated every 2 days by 2 units to obtain a Fasting Plasma Glucose (FPG) of <100 mg/dL (5.6 mmol/L). At baseline, mean age was 58.4 ± 8.3 yrs (mean ± standard deviation), mean type 2 diabetes duration was 9.9 ± 5.8 years, mean FPG was 189.2 ± 48.7 mg/dL, and mean HbA_{1c} was 8.7 ± 0.9%. 27.5% and 25.6% of patients reached the primary endpoint of HbA1c <7% without confirmed hypoglycaemia. Change from baseline to endpoint HbA1c was similar with Lantus® and insulin detemir (-1.46 ±1.09 and -1.54 ± 1.11%; p=0.149), endpoint HbA_{1c} levels were 7.2 ± 0.9% and 7.1 ± 0.9% respectively. Endpoint FBG was lower with Lantus® versus insulin detemir (108 ± 24 vs 119 ± 32mg/dL).

There was a lower rate of daytime symptomatic hypoglycaemia confirmed by PG $\leqslant$ 56 mg/dL (3.1 mmol/L) with Lantus® treatment vs. insulin detemir (1.06 ± 3.13 vs. 1.64 ± 5.42 events/patients-year, p=0.046). Frequencies of asymptomatic, overall symptomatic, nocturnal symptomatic and severe hypoglycaemia were comparable between treatment groups. Significantly more patients in the insulin detemir group terminated the study early (10.1 vs. 4.6%, p=0.001), which was mostly related to skin reactions. Limited weight gain in both groups, although compared with the glargine group, patients on insulin detemir experienced less weight gain (0.6 versus 1.4kg, difference 0.77kg p<0.001).

About Lantus®

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 hyperglycaemia and for adult and paediatric 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 hypoglycaemia and allowing a constant and high efficacy over 24h with one single day injection. Lantus® is the number one prescribed insulin worldwide.

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. In addition, about 40 percent of those diagnosed are not achieving the blood sugar control target of HbA_{1c} < 7 percent recommended by the ADA. The HbA_{1c} 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.

Reference:

(1) S.G.H. Swinnen, et al. Abstract 966. "Once-daily insulin glargine requires a significantly lower dose than insulin detemir twice-daily to achieve good glycaemic control in patients with type 2 diabetes failing oral therapy"

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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