Retrospective Analysis Finds that Initiation of Insulin Glargine in Patients with Type 2 Diabetes was Associated with a Lower Incidence Rate of Myocardial Infarction as Compared with NPH Insulin

Orlando, Florida, November 7, 2007 – A retrospective analysis of healthcare claims in more than 20,000 patients with type 2 diabetes from an integrated U.S. national managed care database found that the initiation of insulin therapy with insulin glargine was associated with a lower incidence rate of subsequent myocardial infarction (MI), as compared with NPH insulin. The new findings, presented at the American Heart Association's 2007 Scientific Sessions, are some of the first to evaluate the rate of MI in a database of patients treated with insulin glargine – a commonly used drug in patients with type 2 diabetes for the control of hyperglycemia.

The unadjusted incidence rate of MI events was 11.5/per thousand patient-years in the group of patients treated with glargine and 17.6/per thousand patient-years in the group treated with NPH during an observation period up to 5 years with a mean about 2 years. The unadjusted hazard ratio for MI events was 0.640 (95% CI: 0.539 - 0.761). After adjusting for multiple patient factors, the risk of MI remained lower in the group of patients who initiated treatment with insulin glargine (HR: 0.73; 0.60 – 0.89) as compared with NPH insulin.

"While insulin glargine has become widely used for the control of hyperglycemia in patients with diabetes since its introduction, the post-market data on its long-term cardiovascular safety has been lacking until now," said Dr. Mikhail Kosiborod, a cardiologist at the Mid America Heart Institute in Kansas City, Missouri, and one of the lead authors of the study. "Although these findings need to be confirmed in future, prospective studies, they suggest that the use of insulin glargine is associated with lower risk of MI than NPH."

Further Studies Planned

The cardiovascular complications associated with diabetes are one of the most serious unmet needs in medicine today. This question is addressed by sanofi-aventis with a comprehensive program evaluating the acute and long-term effects of insulin glargine on cardiovascular outcomes.

As part of this broad effort, the INTENSIVE (Intensive Insulin Therapy and Size of Infarct as a Validated Endpoint by Cardiac MRI) trial will use magnetic resonance imaging to compare the effects of tight glycemic control using insulin glargine and insulin glulisine to usual care on cardiac function (infarction size) in patients with ST-Elevation MI. Results are anticipated in 2009.

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And, the ORIGIN (Outcome Reduction with Initial Glargine Intervention) trial is currently examining the effects of insulin glargine on cardiovascular outcomes in more than 12,000 patients, 50 years of age or older with at least one cardiovascular disease risk factor and pre-diabetes or early type 2 diabetes. ORIGIN is a 5-year, randomized, open-label, multicenter, 2 x 2 factorial design trial. Results are anticipated in 2010.

About the Retrospective Analysis

Using a national managed care administrative database, researchers evaluated medical data from 14,730 type 2 diabetes patients who began treatment with insulin glargine and 5,461 patients who began treatment with NPH during 03/2001 – 03/2005. All of the patients had been using oral anti-diabetic medications during six months prior to initiating treatment with insulin. Cox proportional hazard models were used to compare the rate of subsequent myocardial infarction (MI) events (defined by ICD-9 codes) following initiation of glargine versus NPH, after adjusting for differences in baseline patient characteristics, timing of insulin initiation, concomitant medications, type of health plans and level of medication copayment.

Mean age was 56 years in both insulin groups, 49% were women; mean duration of follow up was 24 months. Among patients who had available A1C (n=2,514), those in the glargine group had higher A1C at baseline versus NPH (9.3 versus 8.9 respectively, p<0,0001). During the first year following insulin initiation, 7.4% of patients in the glargine group versus 8.7% in the NPH group had at least one medical claim for hypoglycemia (Odds Ratio = 0.85, 95% CI: 0.76 - 0.95). Although hypoglycemia incidence was associated with an over 40% increase in the risk of MI (HR=1.42; 1.11-1.83), the difference in hypoglycemia between the two insulin groups did not substantially attenuate the association of insulin initiation with subsequent MI incidence.

This retrospective analysis should not be used to draw definitive conclusions about the potential cardiovascular benefits of insulin glargine or NPH. Additional prospective studies are needed to validate these findings.

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, 2006. 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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