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Appropriate glycemic control contributes to reducing the risk of macrovascular diseases in patients with diabetes

A retrospective analysis from the Integrated Health Care Information System database (IHCIS) of 69,418 patients with diabetes showed that elevated A1C levels were statistically significantly associated with higher risk of macrovascular events. The new findings presented at the European Association for the Study of Diabetes' 43rd Annual Meeting, add to the growing debate in the diabetes community about glycemic control and the cardiovascular risks associated with diabetes.

The Hemoglobin A1C test measures average blood glucose levels over a two- to three-month period. Compared to the group of patients with A1C<6% the hazard risk for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) surgery or stroke was higher in patients with A1C between 7 and 9% by 8% (p<0.01) and 15% (p<0.001) in the A1C≥9% group.

Patients in the data base were 54% male, with a mean age of 57 years, an index A1C 7.6% and a mean follow-up from A1C index of 27 months. The patients were stratified into 4 groups based on index A1C: <6 %, 6 -7 %, 7 -9 %, and ≥9 %. Survival analysis was conducted to examine the first occurrence of acute myocardial infarction, CABG surgery or stroke after index A1C control with patients being censored at the end of their health plan enrollment.

Heart disease and stroke account for approximately 65% of deaths in people with diabetes. This finding demonstrating a high incidence of macrovascular events in diabetic patients with A1C >7% is important because appropriate glycemic control may contribute to reducing the risks of macrovascular diseases in this patients population.

"Elevated A1C level is a significant risk factor for myocardial infarction, coronary artery bypass graft surgery and stroke in patients with diabetes. Early intervention with intensive diabetes treatment may reduce these macrovascular risks," stated Pr. J. M. Foody, Internal Medicine/Section of Cardiology, Yale University School of Medicine, New Haven, United States.

About guidelines

Being the most potent mean of lowering blood sugar levels¹, insulin should be the appropriate treatment to improve cardiovascular outcomes in at-risk patients elevated A1C directly for T1 patients and in spite of appropriate diet and oral antidiabetic treatment for T2 patients.

About Lantus[®] (insulin glargine [rDNA origin])

Lantus[®] is the only 24-hour peakless insulin approved exclusively for use once a day. Most insulins have a "peak of action," which refers to the time at which insulin reaches its maximum effect in the body. With Lantus[®],

the insulin is released into the bloodstream at a relatively constant rate throughout the day and night; therefore it has no pronounced peak.

In type 2 diabetes, the final mean A1C on Lantus[®] ranged from 6.9% to 7.2% in 7 studies where aggressive titration was performed and strict monitoring was used.²⁻⁸

A major clinical trial known as ORIGIN (Outcome Reduction with Initial Glargine INtervention) is currently examining the effects of the long-acting insulin Lantus[®] (insulin glargine [rDNA origin] injection) 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 Diabetes

Diabetes is a chronic, widespread condition in which the body does not produce or properly use insulin – the hormone needed to convert glucose (sugar) into energy. More than 230 million people worldwide are living with the disease. This number is expected to rise to a staggering 350 million within 20 years⁹. It is estimated more than 20 million Americans have diabetes, including an estimated 6.2 million who remain undiagnosed¹⁰. At the same time, approximately half of those diagnosed are not achieving the general blood sugar control standard of A1C <7% recommended by the American Diabetes Association (ADA)¹¹. The A1C test measures average blood glucose levels over a two- to three-month period.

About sanofi-aventis

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe. Backed by a world-class R&D organisation, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. 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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