## Sanofi-aventis Press Release

# Once Daily Lixisenatide (AVE 0010) Given as Monotherapy Successfully Meets Phase III Study Endpoints in Diabetes

- Lixisenatide significantly reduced HbA1c vs placebo with more patients achieving HbA1c <7%
- Significant effect on postprandial glucose

Paris, France – April 15, 2010 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that the results of the first, placebo-controlled study of the GetGoal Phase III clinical trial program showed lixisenatide (AVE0010), a once-daily GLP-1 agonist, significantly reduced HbA1c vs. placebo with more patients achieving HbA1c<7% and improved glycemic control in adult patients with type 2 diabetes.

The complete study findings have been submitted for presentation at the 46<sup>th</sup> Annual Meeting of the European Association for the Study of Diabetes (EASD), in Stockholm, Sweden, in September 2010.

"Developing new diabetes treatments, like lixisenatide, and helping patients achieve diabetes control is paramount to tackling the growing diabetes epidemic," said Dr. Marc Cluzel, Executive Vice-President, R&D, sanofi-aventis. "We are pleased with the top-line results from our first Phase III study of this novel, once-daily GLP-1 agonist and are looking forward to sharing the full results later in the year."

The 12-week study involved 361 patients with type 2 diabetes not currently receiving glucose-lowering therapy and with HbA1c between 7 and 10%. Patients were randomized to one of four once-daily treatment regimens: lixisenatide two-step titration (10  $\mu$ g QD for 1 week, 15  $\mu$ g QD for 1 week then 20  $\mu$ g QD; n=120), lixisenatide one-step titration (10  $\mu$ g QD for 2 weeks then 20  $\mu$ g QD; n=119), placebo two-step titration (n=61), or placebo one-step titration (n=61).

Baseline characteristics were similar among groups in terms of mean age (53.7  $\pm$  10.5 years), diabetes duration (2.5  $\pm$  3.4 years) and HbA1c (8.04  $\pm$  0.9%). HbA1c was significantly reduced in both lixisenatide titration groups versus placebo, and significantly more patients in the lixisenatide groups achieved HbA1c < 7% (46.5 to 52.2% versus 26.8%). as compared to placebo. Lixisenatide also significantly improved fasting plasma glucose and two-hour post-prandial glucose with a pronounced decrease in 2-hour post-prandial glucose excursion.

Lixisenatide was generally well tolerated. The most common adverse event was, as expected with this class of drugs, nausea occurring in 20 to 24% of lixisenatide-treated patients and 4% of placebo patients. The incidence of symptomatic hypoglycemia was low (1.7%) and similar in the lixisenatide and placebo groups.



### **About Lixisenatide (AVE 0010)**

Lixisenatide, a GLP-1, Glucagon-like peptide-1 agonist, is under development for the treatment of patients with type 2 diabetes mellitus. In the Phase IIb study, once-a-day dosing with lixisenatide was shown to be effective in lowering blood sugar with a good tolerability.

The Phase III GetGoal clinical trial program for lixisenatide started in May 2008. It is designed as multicentre, randomized placebo or active-controlled studies and has enrolled more than 4500 patients. The enrollment of the eight other studies of the GetGoal Phase III program assessing efficacy and safety of lixisenatide in adult patients with type 2 diabetes mellitus treated with various oral antidiabetic agents or insulin was completed at the end of 2009. A Phase III program with the combination of lixisenatide / Lantus® (insulin glargine [rDNA] injection) is expected to start later this year.

### **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 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-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 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 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, the Group's ability to benefit from external growth opportunities 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, 2009. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.