Lixisenatide Significantly Reduces HbA1c Without Increasing Hypoglycemia in Patients Uncontrolled on Sulfonylureas

Paris, France – April 12, 2011 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that lixisenatide, a once-daily GLP-1 receptor agonist under development for people with Type 2 diabetes, achieved its primary efficacy objective of significant HbA1c reduction and improved glycemic control from baseline versus placebo. The top-line results also showed that people treated with lixisenatide had a significant decrease in body weight.

The GetGoal-S trial, one of nine studies in the GetGoal Phase III clinical program, investigated the efficacy and safety of lixisenatide as an add-on therapy for people with Type 2 diabetes whose condition was inadequately controlled by sulfonylureas, with or without metformin. GetGoal-S was a randomized (double-blind), placebo-controlled study with a 24-week main treatment period. A total of 859 patients were randomized to receive either lixisenatide or placebo. Both groups received a step-wise increase in dose, up to a maintenance dose of 20µg daily.

Top-line results of the GetGoal-S study showed that people in the lixisenatide group experienced a significant reduction in their HbA1c levels, with a -0.74% difference versus placebo (p<0.0001) at week 24. Lixisenatide also significantly improved patients' 2-hour post-prandial glucose (p<0.0001) and fasting plasma glucose (p<0.0001) levels. In addition, people treated with lixisenatide had a significant decrease in body weight (p<0.0001), versus those receiving placebo.

Results from GetGoal-S also showed that lixisenatide did not significantly increase the risk of symptomatic hypoglycemia at week 24 (p=0.23), compared with placebo.

"The results of GetGoal-S are another positive step for lixisenatide and reinforce the efficacy and safety profile of this new GLP-1," said Pierre Chancel, Senior Vice President, Global Diabetes Division, sanofi-aventis. "The demonstration of benefits in terms of improving glycemic control and reducing body weight in this population, without significantly increasing the risk of symptomatic hypoglycemia, confirmed that lixisenatide is a potential important new therapy in Type 2 diabetes to help people manage their condition more effectively."

The full study findings are planned to be presented at the 47th European Association for the Study of Diabetes (EASD) Annual Meeting, in September 2011.

About Lixisenatide (AVE 0010)

Lixisenatide, a glucagon-like peptide-1 agonist (GLP-1), is in development for the treatment of patients with Type 2 diabetes mellitus. Lixisenatide was in-licensed from Zealand Pharma A/S (Copenhagen, Denmark), www.zealandpharma.com.

GLP-1 is a naturally-occurring peptide that is released within minutes of eating a meal. It is known to suppress glucagon secretion from pancreatic alpha cells and stimulate insulin secretion by



Because health matters

pancreatic beta cells. GLP-1 receptor agonists are in development as an add-on treatment for Type 2 diabetes and their use is endorsed by the European Association for the Study of Diabetes, the American Diabetes Association, the American Association of Clinical Endocrinologists and the American College of Endocrinology.

About the GetGoal Phase III Clinical Program

The GetGoal Phase III clinical program is providing expanding evidence for the efficacy and safety of lixisenatide in adults with Type 2 diabetes treated with various oral anti-diabetic agents or insulin. With nine trials in the program, GetGoal started in May 2008 and has enrolled more than 4300 patients. To date GetGoal-X, GetGoal-Mono and GetGoal-L Asia have reported positive top-line results supporting efficacy and safety for lixisenatide. Further results are expected during 2011.

About the sanofi-aventis Diabetes Division

Sanofi-aventis strives to deliver innovative and integrated patient-focused solutions for people living with diabetes. The Company currently has insulin products that are also available in injection pens for people with Type 1 or Type 2 diabetes, as well as an oral, once-daily sulfonylurea treatment for Type 2 diabetes. In order to provide comprehensive care in diabetes management, sanofi-aventis also provides innovative blood glucose monitoring systems. Investigational compounds in the pipeline include the potential first regenerative treatment for diabetes as well as a once-daily injectable GLP-1 agonist to be used alone, in combination with basal insulins, and/or in combination with oral anti-diabetic agents.

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). For more information, please visit www.sanofi-aventis.com.

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 quarantee 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, 2010. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

Contacts

Marisol Peron Corporate Media Relations Tel: +33 (0)1 53 77 45 02 Mobile: +33 (0)6 08 18 94 78 E-mail: <u>marisol.peron@sanofi-aventis.com</u>

Cornelia Schaeffer Global Diabetes Division Communications Tel: +49 69 305 22353 E-mail: <u>Cornelia.Schaeffer@sanofi-aventis.com</u>