# Once-Daily Lixisenatide in Combination with Basal Insulin Demonstrates Significant Improvement in Glucose Control

**Paris, France – September 30, 2010 –** Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today the top-line results of the GETGOAL-L-ASIA study assessing the efficacy and safety of lixisenatide, a once-daily GLP-1 receptor agonist, in combination with basal insulin. Results from the Phase III study showed that lixisenatide once-daily in combination with basal insulin (with or without sulfonylurea) significantly improved glycemic control. The study also confirmed that there are no specific safety concerns with lixisenatide in patients with type 2 diabetes.

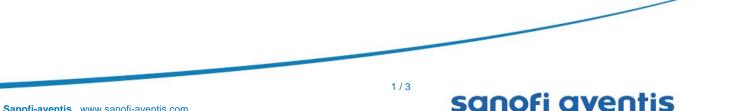
"The results of this study show that lixisenatide once-daily in combination with basal insulin provides a significant reduction in A1C," said Marc Cluzel, M.D., PhD, Executive Vice President, Research & Development, sanofi-aventis. "Adding lixisenatide, a new GLP-1 with a strong post-prandial glucose effect, to a basal insulin may offer patients a new treatment approach to better control glucose and prevent long-term complications."

The GETGOAL-L Asia study was a 24-week, double-blind, placebo-controlled, two-arm parallel-group, multicenter trial and it assessed the safety and efficacy of lixisenatide as add-on therapy in a total of 311 Asian patients with type 2 diabetes insufficiently controlled with basal insulin (with or without sulfonylurea). Patients in the study had a baseline A1C levels between 7 and 10%; were 20 years of age or older, and were diagnosed with type 2 diabetes for at least one year before screening visit. They were randomized to add either lixisenatide once-daily, or placebo to their existing treatment regimen. Sixty percent of patients were taking Lantus<sup>®</sup> (insulin glargine) as their basal insulin.

The study met its primary endpoint, and the addition of lixisenatide once daily to basal insulin significantly reduced A1C levels by 0.88% versus placebo (p<0.0001). The full study findings will be submitted to a medical congress for presentation.

The previously released results of the GETGOAL MONO study, presented earlier this month at the European Association for the Study of Diabetes (EASD) 46<sup>th</sup> Annual Meeting, also showed that lixisenatide once-daily as monotherapy had a significant effect on postprandial blood glucose control and A1C levels. The results of this second study demonstrate the efficacy of lixisenatide in a different population of type 2 diabetic patients.

Lixisenatide was in-licensed from Zealand Pharma A/S (Copenhagen, Denmark).



Because health matters

#### 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 by sanofi-aventis from Zealand Pharma A/S (Copenhagen, Denmark), <u>www.zealandpharma.com</u>. The efficacy and safety of lixisenatide once-daily is being assessed in the GetGoal Phase III clinical trial program. The GetGoal clinical trial program started in May 2008 and has enrolled more than 4,000 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. The next results of the GetGoal Phase III program are expected to be released in Q2 2011.

#### About GLP-1 Receptor Agonists

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 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 EASD, the American Diabetes Association, the American Association of Clinical Endocrinologists and the American College of Endocrinology.

#### 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 hyperglycemia 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 hypoglycemia and allowing a constant and high efficacy over 24h with one single day injection. Lantus® is the number one prescribed insulin worldwide.

### About the sanofi-aventis Diabetes Division

Sanofi-aventis strives to be a 360 degree partner delivering innovative and integrated solutions for people living with diabetes. The Company currently has insulin products that are also available as injection pens for people with type 1 or type 2 diabetes. Following the formation of its Diabetes Division, sanofi-aventis has agreements with other companies for the development of blood glucose monitoring solutions and the potential first regenerative treatment for diabetes. Investigational compounds also in the pipeline include the once-daily injectable GLP-1 agonist lixisenatide alone, in combination with basal insulins including Lantus, and in combination with oral antidiabetic 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: <u>www.sanofi-aventis.com</u>.

#### 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 sanofiaventis, 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.

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