Sanofi Reports Positive Results for Once-daily Lyxumia® (lixisenatide) in Combination with Lantus® (insulin glargine) in Type 2 Diabetes

– Data from phase III GetGoal Duo 1 study show combination helped achieve HbA_{1c} < 7.0% and significantly improved 2-h post-prandial glucose in uncontrolled patients –

Paris, France – December 6, 2011 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that Lyxumia® (lixisenatide), its investigational GLP-1 agonist, in combination with Lantus® (insulin glargine) achieved its primary efficacy endpoint of significantly reducing $HbA_{1c,}$ with a significant improvement in post-prandial glucose, in the GetGoal Duo 1 study (also known as EFC10781*).

Positive topline results of GetGoal Duo1 demonstrated the efficacy and safety of lixisenatide in combination with insulin glargine in patients with type 2 diabetes uncontrolled on oral anti-diabetics (OADs) – mainly metformin.

This randomized, double-blind, placebo-controlled study included a 12-week run-in period with insulin glargine initiated and titrated to reach a target fasting plasma glucose of 80-100 mg/dL followed by a 24-week randomized period where 446 patients with HbA_{1c} >7% - despite controlled fasting plasma glucose - received either lixisenatide once-daily or placebo while insulin glargine and metformin were continued. 88% of patients in the lixisenatide arm reached and remained on the 20 µg maintenance dose.

During the run-in period, HbA_{1c} decreased on average from 8.60% to 7.60%. After randomization the addition of lixisenatide led to a further significantly greater HbA_{1c} decrease compared with placebo ($p<0.0001$) to a mean value of 6.96% after 24 weeks with a significantly higher percentage of patients achieving target HbA_{1c} <7.0% with lixisenatide vs. placebo (56.3% vs. 38.5%, respectively, $p=0.0001$).

Lixisenatide also significantly improved 2-h post-prandial glucose with a mean difference of -3.16 mmol/L ($p<0.0001$) vs placebo. The mean difference in change in body weight between the lixisenatide and placebo groups was -0.89 kg ($p=0.0012$).

Consistent with the GLP-1 class, the most common adverse events were mild and transient nausea and vomiting. Fifty (22.4%) lixisenatide-treated patients and 30 (13.5%) patients in the placebo group reported symptomatic hypoglycemic events as defined in the protocol during the on-treatment period.

"*Lixisenatide is a promising new GLP-1 agonist with a mode of action which complements that of basal insulin. Added once-daily to optimally titrated Lantus®, it safely improved HbA_{1c} with beneficial effects on both post-prandial glucose and body weight,*" commented Dr. Matthew Riddle, Professor of Medicine and Head of the Diabetes Division at the Oregon Health and Science University, Portland, U.S.

"This is another key milestone in the clinical development program for our new GLP-1 agonist," declared Pierre Chancel, Senior Vice-President of Sanofi Diabetes. *"Achieving glycemic control and compliance with treatment is a complex challenge. These positive results show that once-daily lixisenatide in combination with Lantus® could be an innovative therapeutic option for the treatment of uncontrolled type 2 diabetes by addressing its pathophysiology especially regarding post-prandial glucose control with a convenient once-daily regimen, helping those patients who fail to meet HbA1c target despite controlled fasting plasma glucose."*

On November 16th, 2011 the European Medicines Agency (EMA) accepted Sanofi's marketing authorization application filed for Lyxumia® (lixisenatide). Submission for regulatory approval of lixisenatide in the U.S. is expected in Q4 2012.

The full study results from GetGoal Duo 1 are planned to be presented at a future medical congress.

About Lyxumia® (lixisenatide)

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. Lyxumia® is the intended trademark of lixisenatide. Lixisenatide is not currently approved or licensed anywhere in the world.

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 European Association for the Study of Diabetes, the American Diabetes Association, the American Association of Clinical Endocrinologists and the American College of Endocrinology.

The GetGoal phase III clinical program provides data for lixisenatide in adults with type 2 diabetes treated in monotherapy, with various oral anti-diabetic agents or in combination with basal insulin. The GetGoal program started in May 2008 and has enrolled more than 4,500 patients. To date, GetGoal-X, GetGoal-L, GetGoal-L Asia, GetGoal-Mono, GetGoal-S, GetGoal-F1 and GetGoal Duo 1 (also known as EFC10781*) have reported positive top-line results supporting potential efficacy and safety for lixisenatide. Further results are expected in 2012.

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services, and devices. Sanofi markets both injectable and oral medications for people with type 1 or type 2 diabetes. Investigational compounds in the pipeline include an injectable GLP-1 agonist being studied as a single agent, in combination with basal insulin, and/or in combination with oral antidiabetic agents.

About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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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's 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, 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 labeling 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, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2010. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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