Lyxumia® (lixisenatide) One-Step Regimen as Effective as Two-Step Regimen in Improving Glycemic Control in Type 2 Diabetes

- New phase III data from GetGoal-F1 study of once-daily lixisenatide support simplified treatment initiation -

- Study results presented at the European Association for the Study of Diabetes (EASD) 47th Annual Meeting -

Paris, France – September 12, 2011 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that Lyxumia® (lixisenatide), a once-daily GLP-1 receptor agonist under development for type 2 diabetes, achieved its primary efficacy endpoint of significant HbA_{1c} reduction vs. placebo in patients uncontrolled on metformin. The study objectives were to compare the efficacy and safety of lixisenatide versus placebo in one-step and two-step dose increase regimens in terms of reduction in HbA_{1c}.

"Efficacy and Safety of Lixisenatide Once-Daily Versus Placebo in Patients with Type 2 Diabetes Insufficiently Controlled on Metformin (GetGoal-F1)" [ABSTRACT 784]

The GetGoal-F1 trial, one of nine studies in the GetGoal clinical program, was a randomized, double-blind, placebo-controlled, parallel group, multicenter study with a 24-week main treatment period. A total of 482 people with type 2 diabetes were randomized and exposed to one of the following once-daily regimens: lixisenatide one-step dose increase (10µg for two weeks, then 20µg); lixisenatide two-step dose increase (10µg for one week, 15µg for one week, then 20µg), or placebo, as add on to metformin.

Top-line results show that lixisenatide significantly reduces HbA_{1c} from baseline to week 24 in both treatment regimens, compared with placebo (one-step: -0.92%; two-step: -0.83% vs. placebo: -0.42%; $p<0.0001$). The percentage of patients reaching HbA_{1c} targets of ≤ 6.5% and HbA_{1c} < 7.0% with the one-step regimen was 25.6% and 47.4% and with the two-step regimen was 20.4% and 42.1% versus 7.6% and 24.1% with placebo, respectively.

In addition, both one- and two-step regimens reduced body weight: one-step: -2.63kg; two-step: -2.68kg versus placebo: -1.63kg; (p-value 1-step = 0.0042; p-value 2-step = 0.0025).

"*The GetGoal-F1 study shows that, in people with type 2 diabetes not achieving adequate glycemic control*, *lixisenatide once daily as 'add on' to metformin is effective in both improving glycemic control and reducing body weight, and the one-step dose increase regimen may be the best option for treatment initiation,"* said Geremia Bolli, MD, of the University of Perugia, Italy and lead investigator of the GetGoal-F1 study.

The percentage of patients who discontinued during the main 24-week treatment period due to adverse events was 5.6% in the one-step regimen, 8.1% in the two-step regimen versus 2.5% with placebo. Overall, lixisenatide was well tolerated and gastrointestinal event levels were as expected for the GLP-1 class. The most frequently reported adverse events were nausea (26.1% [1-step], 35.4% [2-step] vs. 4.4% with placebo) and vomiting (11.8% [1-step], 15.5% [2-step] vs. 0% with placebo). There was no increased risk of severe hypoglycemia.

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 for 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 will provide data for 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 4,300 patients. To date, GetGoal-X, GetGoal-L, GetGoal-L Asia, GetGoal-Mono and GetGoal-S have reported positive top-line results supporting efficacy and safety for lixisenatide. Further results are expected during 2011.

About the Sanofi Diabetes Division

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insight that comes 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 insulins, 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).

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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