



Positive Results for Investigational Compound Lyxumia® (Lixisenatide) Presented at American Diabetes Association's 71st Annual Scientific Sessions

- *Once-Daily Lyxumia® Demonstrates Non-Inferior Reduction of Blood Glucose and Less Hypoglycemia versus Exenatide Twice Daily in Type 2 Diabetes Patients -*
- *Once-Daily Lyxumia® in Combination with Basal Insulin Improves Glycemic Control in Asian Type 2 Diabetes Patients -*

Paris, France – June 24, 2011 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today data from four studies of its once-daily GLP-1 receptor agonist Lyxumia® (lixisenatide) that is in Phase III clinical development, including data that demonstrates positive results in type 2 diabetes patients not at goal on oral therapies or with basal insulin. These data are being presented or published at the American Diabetes Association's 71st Scientific Sessions in San Diego, California.

“Efficacy and Safety of Lixisenatide Once-Daily Versus Exenatide Twice-Daily in Type 2 Diabetes Inadequately Controlled on Metformin (GetGoal-X)” [ABSTRACT 0033-LB]

“Lixisenatide once daily demonstrated efficacy in blood glucose control by meeting an endpoint of non-inferiority at week 24 in a head-to-head study versus exenatide twice daily,” said Julio Rosenstock, MD, director of the Dallas Diabetes and Endocrine Center at Medical City Dallas and lead investigator of the GetGoal-X trial.

In the GetGoal-X trial, a randomized, open-label, active-controlled, two-arm parallel-group, multicenter study with a 24-week main treatment period, lixisenatide once daily achieved its primary endpoint of non-inferiority in A1C reduction from baseline with less symptomatic hypoglycemia (low blood sugar) and better gastrointestinal tolerability versus exenatide twice daily, as an add-on to metformin in patients with type 2 diabetes. A total of 634 people were randomized to receive either lixisenatide or exenatide. Both groups received a stepwise increase in dose, up to a maximum daily dose of 20µg. At baseline, the mean age in the trial was 57.4 years, mean diabetes duration 6.8 years, mean body mass index (BMI) 33.6 kg/m² and mean A1C 8.0 percent.

Key Findings:

- Lixisenatide once daily achieved its primary endpoint of non-inferiority in A1C reduction versus exenatide twice daily (LS mean ± SE change from baseline: -0.79 ± 0.05 vs. -0.96 ± 0.05)
- Improvements in mean fasting plasma glucose – measurement of blood glucose levels when a patient is fasting – (LS mean ± SE change from baseline: -22.0 ± 2.1 vs. -26.1 ± 2.1) and the percentage of patients achieving the study target A1C < 7.0 percent (48.5% vs. 49.8%) were comparable between groups
- Mean body weight significantly decreased from baseline in the lixisenatide group compared to the exenatide group (94.5 to 91.7 kg with lixisenatide vs. 96.7 to 92.9 kg with exenatide)



- The proportion of patients with serious adverse events was generally comparable between groups
- Discontinuations due to adverse events (mainly gastrointestinal events including nausea, diarrhea and vomiting) were 33 (10.4%) in the lixisenatide group and 41 (13.0%) in the exenatide group
- Significantly fewer patients experienced symptomatic hypoglycemia with lixisenatide (2.5% vs. 7.9%, $p < 0.05$), with 6-fold fewer hypoglycemic events (8 vs. 48) versus exenatide
- More lixisenatide patients tolerated the target dose of 20 μg per day and completed the trial versus the exenatide 10 mcg target dose (93% vs. 83%)

“Lixisenatide Significantly Improves Glycemic Control in Asian Patients with Type 2 Diabetes Insufficiently Controlled on Basal Insulin \pm Sulfonylurea” [ABSTRACT 0278-OR]

Data from the GetGoal-L Asia trial, showed in Asian patients with type 2 diabetes insufficiently controlled by basal insulin \pm sulfonylurea, that lixisenatide once daily significantly improved glycemic control (as measured by the number of patients reaching a target A1C < 6.5 percent or < 7.0 percent) versus placebo at week 24 with a pronounced post-prandial glucose and fasting plasma glucose effect, and was well tolerated.

Key Findings:

- Lixisenatide once daily significantly improved A1C versus placebo (LS mean difference - 0.9%)
- Significantly more lixisenatide patients achieved A1C ≤ 6.5 percent (17.8%) and < 7.0 percent (35.6%) versus placebo (1.3% and 5.2%; $p < 0.0001$)
- Lixisenatide significantly improved two-hour post-prandial glucose, glucose excursion and average 7-point self-measured plasma glucose (SMPG) over placebo (LS mean \pm SE change from baseline: 7.96 ± 0.598 vs. -0.14 ± 0.563 , $p < 0.0001$; -7.09 ± 0.576 vs. 0.14 ± 0.542 , $p < 0.0001$; -1.91 ± 0.272 vs. -0.56 ± 0.271 , $p < 0.0001$, respectively)
- Lixisenatide was well tolerated and 86 percent of patients in the lixisenatide group completed the study versus 92 percent on placebo
- Nine placebo patients (5.7%) and ten lixisenatide patients (6.5%) experienced a serious treatment emergent adverse event and more lixisenatide patients (14 [9.1%]) discontinued participation in the study due to treatment emergent adverse events than placebo patients (5 [3.2%]), mainly due to gastrointestinal adverse events
- As expected in an insulin \pm sulfonylurea-treated population, the percentage of patients with symptomatic hypoglycemia was higher with lixisenatide (42.9%) versus placebo (23.6%); the rate decreased to 31.8 percent versus 28.3 percent in those not receiving sulfonylurea
- There were no cases of severe hypoglycemia

“Cardioprotective Effect of the GLP-1 Receptor Agonist Lixisenatide on Ischemia-Reperfusion-Induced Injury in the Isolated Rat Heart” [ABSTRACT 0968-P]

In this pre-clinical study, data showed that lixisenatide once daily protects against myocardial ischemia-reperfusion injury (tissue damage caused by restriction of oxygen rich blood to the heart) in isolated rat hearts by significantly reducing myocardial infarct size (measurement of damage to the heart) in the isolated rat heart model.

Key Findings:

- Administration of lixisenatide at 0.3 nM starting ten minutes prior to and during reperfusion significantly reduced myocardial infarct-size by 36 percent ($p = 0.0028$ versus vehicle control)



- The observed cardioprotective effect was not associated with a significant change in cardiac hemodynamics (mechanisms involved in circulation), particularly coronary flow, suggesting a direct cardiac effect

“Effect of the Once-Daily GLP-1 Receptor Agonist Lixisenatide on Gastric Emptying and Prandial Carbohydrate Utilization in Animal Models: A Comparison with Liraglutide” [ABSTRACT 2267-PO]

Data from several animal studies showed that treatment with lixisenatide was more effective in delaying gastric emptying and lowering prandial glucose excursions (change in glucose concentration after a meal) than liraglutide.

Key Findings:

- Lixisenatide strongly and dose-dependently inhibited gastric emptying in rats with a significant emptying effect already present at 1 µg/kg sc
- Even a 100 times higher dose of liraglutide was ineffective and significant inhibition of gastric emptying was observed only at doses of 500 µg/kg and above
- In an oral glucose tolerance test in dogs, 1 µg/kg sc lixisenatide almost completely abolished blood glucose excursion
- With liraglutide, the glucose-lowering effect during oral glucose tolerance testing was significantly weaker than that of lixisenatide, even when liraglutide was administered at 50-100 times higher doses
- After administration of a liquid meal, lixisenatide (3 µg/kg sc) given to mice was more effective in lowering prandial glucose excursions than liraglutide (200 µg/kg) and lixisenatide (10 µg/kg) injected subcutaneously to diabetic mice improved glucose tolerance at least as effectively as liraglutide (200 µg/kg sc)

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-Mono and GetGoal-L Asia and GetGoal-S, have reported positive top-line results supporting efficacy and safety for lixisenatide. Further results are expected during 2011.

About Diabetes

Diabetes is a chronic, widespread condition characterized by high blood sugar 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. It is estimated that approximately 285 million adults worldwide are living with the disease and this number is expected to rise to a staggering 438 million



within 20 years. It is estimated that nearly 26 million Americans have diabetes, including an estimated 7 million who remain undiagnosed. At the same time, approximately 40 percent of those diagnosed with diabetes did not achieve the blood sugar control target of A1C <7 percent recommended by the American Diabetes Association. The A1C test measures average blood glucose levels over the past two-to-three-month period.

About the Sanofi Diabetes Division

Sanofi strives to help people manage the complex challenges 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.

Contacts:

US Communications

Susan Brooks
T. 908-981-6566
Susan.Brooks@sanofi-aventis.com

Global Communications

Yanyan Chang
T. +49 69 305 22283
Yanyan.chang@sanofi-aventis.com

Corporate Media Relations

Marisol Péron
Tel: +33 (0) 1 53 77 45 02
Mobile: +33 (0) 6 08 18 94 78
E-mail: marisol.peron@sanofi.com