Lyxumia® (lixisenatide) in Combination with Basal Insulin plus Oral Anti-Diabetics Significantly Reduced HbA_{1c} and Post-Prandial Glucose

- Lixisenatide with basal insulin helped type 2 diabetes patients with uncontrolled HbA_{1c} achieve target blood glucose levels -

- Lixisenatide marketing authorization application submitted to European Medicines Agency and U.S. FDA submission expected in Q4 2012 -

Paris, France - June 9, 2012 - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today data demonstrating Lyxumia®* (lixisenatide), a once-daily investigational GLP-1 agonist, in combination with basal insulin plus oral anti-diabetic agents (OADs), significantly reduced HbA_{1c} - glycated hemoglobin - in people with type 2 diabetes who were either new to insulin therapy (as early as 12 weeks after initiation) or already treated with insulin (for an average of 3.1 years).

Both GetGoal Duo 1[1] and GetGoal-L[2] studies achieved the primary efficacy endpoint of HbA_{1c} improvement with an associated significant reduction in post-prandial glucose (PPG).

"Treatment with basal insulin and oral agents often controls fasting glucose and achieves glycemic goals for type 2 diabetes, but some patients may need additional treatment to further address post-prandial hyperglycemia. These results with lixisenatide are encouraging and provide scientific support as a potential approach for these patients," commented Dr. Matthew Riddle, Professor of Medicine in the Division of Endocrinology, Diabetes & Clinical Nutrition at Oregon Health & Science University, U.S.

"Efficacy and Safety of Once-Daily Lixisenatide Added on to Titrated Glargine plus Oral Agents in Type 2 Diabetes: GetGoal Duo 1 Study" [Abs A-4452]

GetGoal Duo 1 is a randomized, double-blind, multicenter study, assessing the efficacy and safety of lixisenatide, compared to placebo, in combination with insulin glargine and OADs (mostly metformin). During the 12-week run-in phase, 898 insulin-naïve patients were treated with insulin glargine, which was titrated to reach a target fasting plasma glucose (FPG) of 80-100 mg/dL.

After the run-in phase, 446 patients with HbA_{1c} >7% (despite controlled FPG levels) received either once-daily lixisenatide 20 µg or placebo for 24 weeks while metformin and insulin glargine titration were continued.

HbA_{1c} decreased on average from 8.60% to 7.60% during the run-in period with insulin glargine. The addition of lixisenatide led to a further significant HbA_{1c} decrease to a mean value of 6.96% after 24 weeks compared to 7.3% in patients receiving placebo ($p<0.0001$). A significantly higher percentage of patients achieved target HbA_{1c} <7.0% with lixisenatide compared to placebo (56.3% vs. 38.5%, respectively, $p=0.0001$).

Associated with HbA_{1c} reduction, lixisenatide also significantly improved 2-hour PPG, after a standardized breakfast, with a mean difference of -3.16 mmol/L ($p<0.0001$) compared to placebo.

The mean difference in change in body weight between the lixisenatide and placebo groups was -0.89 kg (p=0.0012).

Incidence of symptomatic hypoglycemia was 22.4% among patients receiving lixisenatide vs. 13.5% in the placebo group. Other common adverse events in the lixisenatide group were nausea and vomiting, which occurred in 27.4% and 4.9%, respectively, compared to placebo (9.4% and 1.3%, respectively). Eighty-eight percent of patients in the lixisenatide arm reached and remained on the 20 µg maintenance dose.

"Efficacy and Safety of Once-Daily Lixisenatide in Type 2 Diabetes Insufficiently Controlled with Basal Insulin ± Metformin: GetGoal-L Study" [A-4379]

Also announced at the American Diabetes Association 72nd congress were data from GetGoal-L, a 24-week randomized, double-blind multicenter, placebo-controlled study of 495 people with type 2 diabetes, insufficiently controlled on basal insulin with or without metformin. In the lixisenatide arm, mean HbA_{1c} was significantly reduced from baseline compared to placebo (-0.74% vs. -0.38%, p=0.0002) along with a significant decrease in mean 2-hour PPG (-5.54 mmol/L vs. -1.72 mmol/L, p<0.0001), after a standardized breakfast.

Patients in the lixisenatide arm of the study also experienced a significant mean reduction in body weight compared to placebo (-1.8 kg vs. -0.52 kg, p<0.0001). The incidence of per protocol symptomatic hypoglycemia was 27.7% for lixisenatide vs. 21.6% for placebo. Severe hypoglycemia occurred in 1.2% of patients treated with lixisenatide compared to none with placebo. Other common adverse events were nausea (26.2%), vomiting (8.2%), and diarrhea (7.3%).

Pierre Chancel, Senior Vice-President, Global Diabetes at Sanofi, added: "*Due to the complexities in type 2 diabetes management, it is important to address the needs of all patients who are not at goal HbA_{1c}, despite achieving, or nearly achieving, controlled fasting plasma glucose (FPG) targets with basal insulin. The results from GetGoal Duo 1 and GetGoal-L are encouraging and we will continue to evaluate Lyxumia® (lixisenatide), with its pronounced post-prandial glucose (PPG) lowering effect, for its potential use in people with type 2 diabetes.*"

The European Medicines Agency (EMA) acknowledged receipt of the Marketing Authorization Application filing for Lyxumia® (lixisenatide) in November 2011. Submission for regulatory approval of lixisenatide in the U.S. is expected in Q4 2012.

The full study results from the GetGoal program are planned for publication in a peer-reviewed medical journal later this year.

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.

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, has enrolled more than 5,000 patients and serves as support for the application for regulatory approval of lixisenatide.

*Lyxumia is the proprietary name submitted to the EMA for the company's investigational GLP-1 agonist lixisenatide. The proprietary name for lixisenatide in the United States is under consideration.

About Diabetes

Diabetes is a long-term disease that occurs either when the pancreas does not produce enough insulin (the hormone that regulates blood glucose concentrations), or when the body cannot effectively use the insulin it produces, or both. This results in raised blood glucose concentrations (hyperglycemia). Over time, uncontrolled hyperglycemia leads to the macrovascular and microvascular complications of diabetes.[4] Macrovascular complications, which affect the large blood vessels, include heart attack, stroke and peripheral vascular disease. Microvascular complications affect the small blood vessels of the eyes (retinopathy), kidney (nephropathy) and nerves (neuropathy). The incidence of type 2 diabetes is growing at an alarming rate, with over 310 million people worldwide living with the condition today.[3]

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, including innovative blood glucose monitoring systems. 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 anti-diabetic agents.

To view the Sanofi ADA electronic press packet, please go to www.epresspack2.net/Sanofi-at-ADA/

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, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

References

1. GetGoal Duo 1 (NCT00975286 www.clinicaltrials.gov) # 062-OR
2. GetGoal-L (NCT00715624 www.clinicaltrials.gov) #2012-A-4379-
3. World Health Organisation diabetes fact sheet, August 2011
4. UK Prospective Diabetes Study (UKPDS) Group, Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33), *Lancet* 1998;352(9131):837-853

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 labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product 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, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding 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, 2011. 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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