



Lyxumia[®] (lixisenatide)* in Combination with Basal Insulin plus Oral Anti-Diabetics Significantly Improved Glycemic Control

– Data show investigational GLP-1 receptor agonist delayed gastric emptying and significantly reduced post-prandial glucose –

– Results from the GetGoal Duo 1 and GetGoal-L Phase III studies also presented at the annual EASD meeting –

Paris, France – October 2, 2012 – Sanofi (EURONEXT: SAN and NYSE: SNY) today announced results from a study showing that the mechanism of action of once-daily Lyxumia[®] (lixisenatide) significantly delayed gastric emptying, a process accompanied by significant post-prandial glucose (PPG) lowering. These data were presented at the 48th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Berlin, alongside Phase III trial results that support the clinical rationale for lixisenatide as a potential once-daily GLP-1 receptor agonist (RA) in combination with basal insulin.

“Effects of lixisenatide once daily on gastric emptying and its relationship to postprandial glycaemia in type 2 diabetes mellitus” [Abs 808-EASD]

Treatment after a standardized breakfast with a final dose of once-daily 20µg lixisenatide and up to two OADs contributed significantly to slowing the rate of gastric emptying, compared with placebo (p=0.0031) in this 28-day, randomized, double-blind, placebo-controlled, parallel-group study in patients with type 2 diabetes (lixisenatide n=19; placebo n=22; final dose reached after titrating from 5–20µg with 2.5µg increments every 4 days). This had a pharmacodynamic effect on blood glucose levels throughout the day. Delayed gastric emptying is associated with lower PPG levels. At day 28, PPG was significantly reduced after a standardized breakfast (p<0.0001), after lunch (p=0.0004) and after dinner (p=0.0082). No such relationship was found for placebo.

“Gastric emptying, the rate at which food passes through the stomach into the intestine, is modulated by GLP-1 and is a major determinant of PPG in both health and diabetes,” explained Professor Michael Horowitz from the Royal Adelaide Hospital, Australia. *“Not all GLP-1 RAs are the same. Those, such as lixisenatide, that are associated with a sustained deceleration of gastric emptying with a consequent significant reduction in PPG levels are likely to best complement the FPG-lowering effect of basal insulin to help type 2 diabetes patients achieve their target HbA_{1c}.”*

“Once-daily lixisenatide added on to consistently titrated insulin glargine plus oral agents in type 2 diabetes: The GetGoal Duo 1 study” [Abs 807-EASD] and “Efficacy and safety of once-daily lixisenatide in type 2 diabetes insufficiently controlled with basal insulin ± metformin: GetGoal-L study” [Abs 3-EASD]

Also presented at EASD (and previously at the American Diabetes Association [ADA] scientific sessions 2012) were results from the GetGoal Duo 1¹ and GetGoal-L² studies, which demonstrated that lixisenatide in combination with basal insulin plus oral anti-diabetic agents (mostly metformin in GetGoal Duo 1, with or without metformin in GetGoal-L) significantly reduced HbA_{1c} – glycated



hemoglobin A_{1c} – 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), respectively.

GetGoal Duo 1 and GetGoal-L both achieved the primary efficacy endpoint of HbA_{1c} improvement with an associated significant reduction in PPG. Results showed that lixisenatide caused mild and transient nausea and vomiting, the most common adverse events, and a limited additional or comparable risk of hypoglycemia.

These studies are part of the GetGoal Phase III clinical program for lixisenatide, which includes a broad range of patients with type 2 diabetes, including a large number of patients treated with basal insulin (706 patients in three trials).³

To achieve target blood glucose levels, both fasting plasma glucose (FPG) and PPG need to be addressed.⁴ Despite basal insulin therapies providing effective FPG control, due to disease progression some patients over time might no longer be at their glycemic targets and need additional treatment to further address uncontrolled HbA_{1c}. A GLP-1 that has a pronounced PPG effect in combination with basal insulin may therefore be beneficial for those patients.

“The positive data for Lyxumia[®] (lixisenatide) are of particular significance as the new Position Statement of the ADA and EASD recognizes that combining therapies may be helpful,” said Pierre Chancel, Senior Vice-President, Global Diabetes at Sanofi. *“Taken together, the results from the GetGoal Duo 1 and GetGoal-L trials, as well as lixisenatide’s significant effect on gastric emptying and PPG, support the clinical rationale for the potential use of our investigational GLP-1 receptor agonist in combination with basal insulin to improve glycemic control by addressing both PPG and FPG.”*

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 December 2012.

About Lyxumia[®] (lixisenatide)

*Lixisenatide, a glucagon-like peptide-1 receptor agonist (GLP-1 RA), is in development for the treatment of patients with type 2 diabetes mellitus. Lixisenatide was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com. Lyxumia[®] is the proprietary name submitted to the EMA for the company’s investigational GLP-1 RA lixisenatide. The proprietary name for lixisenatide in the United States is under consideration. Lixisenatide is not currently approved or licensed anywhere in the world.

GLP-1 is a naturally-occurring peptide hormone that is released within minutes after eating a meal. It is known to suppress glucagon secretion from pancreatic alpha cells and stimulate glucose-dependent 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.

About Diabetes

Diabetes is a chronic disease that occurs as type 1 diabetes, which is an autoimmune disease characterized by the lack of insulin (the hormone that regulates blood glucose concentrations) production by the pancreas, and type 2, a metabolic disorder in which there are two main biological defects: a deficient production of insulin and reduced ability of the body to respond to the insulin being produced. Type 1 and type 2 diabetes are characterized by an increase in blood glucose



concentrations (hyperglycemia). Over time, uncontrolled hyperglycemia leads to the macrovascular and microvascular complications of diabetes. 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). More than 18 million people worldwide are living with type 1 diabetes.⁵ And, the incidence of type 2 diabetes is growing at an alarming rate, with nearly 348 million people worldwide living with the condition today.⁵

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 receptor agonist being studied as a single agent, in combination with basal insulin, and/or in combination with oral anti-diabetic 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, 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. Rosenstock et al. *Diabetes Care* 2012; 35: A18 (62-OR)
2. Riddle et al. *Diabetes Care* 2012; 35: A251 (983-P)
3. <http://clinicaltrials.gov/ct2/results?term=GetGoal>. Date assessed: Aug 2012
4. Riddle. M et al. *Diabetes Care*. 2011; 34: 2508-2514
5. IDF Diabetes Atlas, 5th Edition (2012)

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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