Sanofi Receives Positive CHMP Opinion in the European Union for Once-Daily Lyxumia® (lixisenatide)

- Diabetes portfolio poised to significantly expand in 2013 to meet patient needs -

Paris, France - November 16, 2012 - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending the approval of once-daily Lyxumia® (lixisenatide) for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control. The CHMP positive opinion will now be forwarded to the European Commission (EC), which has the authority to approve medicines for the European Union. Following EC marketing authorization, which is typically granted 2–3 months after a positive opinion, Lyxumia will significantly expand the company's diabetes franchise.

"The CHMP positive opinion for Lyxumia marks an important milestone in the development of this compound and brings us one step closer to serving even more patients by expanding the Sanofi Diabetes product portfolio," said Pierre Chancel, Senior Vice-President, Global Diabetes at Sanofi. *"This recommendation validates our belief that Lyxumia, a once-daily GLP-1 receptor agonist with a pronounced post-prandial glucose lowering effect, is a promising medicine that can be combined with other treatments, such as basal insulin, to help patients with type 2 diabetes achieve target HbA_{1c} levels. We look forward to receiving the European Commission decision."*

The CHMP positive opinion is based on results from the GetGoal Phase III clinical trial program, which examined the efficacy, safety and tolerability profile of Lyxumia.[1] In the GetGoal program, once-daily Lyxumia significantly reduced HbA_{1c} – glycated haemoglobin – in patients with type 2 diabetes (primary endpoint) and showed an associated significant reduction in post-prandial glucose and a beneficial effect on body weight. The GetGoal program also showed that Lyxumia was well-tolerated overall, with only mild and transient adverse effects (primarily nausea, vomiting and diarrhoea) and a limited risk of hypoglycaemia. The international GetGoal program included 11 clinical trials involving more than 5,000 patients with type 2 diabetes, with a large number of patients studied to evaluate a GLP-1 receptor agonist in combination with basal insulin (706 patients in three trials).[1]

In addition to the European Union, lixisenatide has been submitted for regulatory approval in 11 countries. Submission of a New Drug Application to the United States Food and Drug Administration is planned for 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 trial 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 characterised 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 characterised by an increase in blood glucose concentrations (hyperglycaemia). Over time, uncontrolled hyperglycaemia 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.[2] And, the incidence of type 2 diabetes is growing at an alarming rate, with nearly 348 million people worldwide living with the condition today.[2]

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. http://clinicaltrials.gov/ct2/results?term=GetGoal. Date accessed: October 2012
2. IDF Diabetes Atlas, 5th Edition (2012)

Forward Looking Statement

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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