Once-Daily Lyxumia® (lixisenatide) Approved for Treatment of Type 2 Diabetes in Europe

- Sanofi portfolio expands to offer first once-a-day prandial GLP-1 receptor agonist -

Paris, France – February 4, 2013 - Sanofi (EURONEXT : SAN and NYSE : SNY) announced today that the European Commission has granted Marketing Authorisation in Europe for Lyxumia® (lixisenatide). Lyxumia®, the first once-daily prandial GLP-1 receptor agonist, is indicated 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.

"With the European approval of Lyxumia®, we now have a simple new tool to help patients with type 2 diabetes further reduce HbA_{1c}, with the benefit of weight loss and limited risk of hypoglycaemia. This well-tolerated therapy is of specific interest to patients who are on oral treatments and / or basal insulin and do not manage to maintain their HbA_{1c} targets," said Pierre Chancel, Senior Vice-President, Global Diabetes at Sanofi. *"With a single daily injection and only one step to maintenance dose, Lyxumia® is a positive addition to the Sanofi portfolio, and represents another step forward in our efforts to advance scientific excellence and develop new therapeutic solutions that improve outcomes for people with diabetes, an area of significant unmet medical need."*

The European Commission decision to grant Marketing Authorisation in Europe for Lyxumia® is based on results from the GetGoal clinical programme, which enabled Lyxumia® to be the first once-daily GLP-1 receptor agonist with a predominantly prandial glucose lowering effect to be indicated for use on top of basal insulin and in combination with oral anti-diabetic medications. The clinical programme showed that Lyxumia® demonstrated significant HbA_{1c} reductions, a pronounced post-prandial glucose lowering effect and a beneficial effect on body weight in adult patients with type 2 diabetes. GetGoal results also showed that Lyxumia® had a favourable safety and tolerability profile in most patients, with mild and transient nausea and vomiting, the most common adverse events observed in the GLP-1 receptor agonist class, and a limited risk of hypoglycaemia. The international GetGoal programme 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 treated with Lyxumia® in three trials).[1]

"*Lyxumia® in combination with oral and / or basal insulin therapies can play a key role in meeting the important need to maintain HbA_{1c} targets for people with type 2 diabetes,*" said Dr. Bo Ahrén, MD, PhD, from Lund University in Sweden. "*Basal insulin therapies, while targeting fasting plasma glucose, are able to provide effective control of overall glucose excursion and are able to bring many patients to the target HbA_{1c} level. However, as diabetes progresses over time, patients treated with basal insulin may no longer stay at their HbA_{1c} goals, despite good control of fasting plasma glucose. When this happens, adding a medicine such as Lyxumia®, which has a pronounced post-prandial glucose lowering effect, may be an effective strategy to further lower blood glucose levels and maintain HbA_{1c} goals.*"

Marketing Authorisation in Europe for Lyxumia® is applicable to the 27 Member States of the European Union, as well as Iceland, Lichtenstein and Norway, and follows the 15 November 2012 positive opinion issued by the Committee for Medicinal Products for Human Use of the European Medicines Agency. Applications for regulatory approval were also submitted in several other countries around the world and are being reviewed.

About Lyxumia® (lixisenatide)

Lyxumia® is a glucagon-like peptide-1 receptor agonist (GLP-1 RA) for the treatment of patients with type 2 diabetes mellitus. 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.

Lyxumia® was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com. Lyxumia® is the proprietary name approved by the European Medicines Agency (EMA) for the GLP-1 RA lixisenatide.

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalised 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.

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).

Reference

1. http://clinicaltrials.gov/ct2/results?term=GetGoal. Date accessed: December 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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