Sanofi New Drug Application for Lixisenatide Accepted for Review by FDA

Paris, France - February 19, 2013 – Sanofi (EURONEXT : SAN and NYSE : SNY) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for lixisenatide, the first once-daily prandial GLP-1 receptor agonist for the treatment of adults with type 2 diabetes mellitus. The acceptance of the lixisenatide NDA filing follows the February 1, 2013, European Commission approval of lixisenatide in the European Union.

"We are very pleased to announce the FDA acceptance of our submission for lixisenatide in the U.S.," said Pierre Chancel, Senior Vice President, Global Diabetes at Sanofi*. "This important milestone is the result of our company's continuing worldwide effort to meet the needs of people living with diabetes, and we look forward to working with the FDA during the review process."*

The NDA submission for lixisenatide is based on results from the GetGoal clinical program, which showed that lixisenatide demonstrated significant reductions in HbA_{1c}, a pronounced post-prandial glucose (PPG)-lowering effect and a beneficial effect on body weight in adult patients with type 2 diabetes. GetGoal results also showed that lixisenatide had a favorable 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 hypoglycemia.

The international GetGoal program included 11 clinical trials involving more than 5,000 patients with type 2 diabetes,[1] with a large number of patients studied to evaluate a GLP-1 receptor agonist in combination with basal insulin (1,250 patients treated with lixisenatide or placebo in three trials). The addition of lixisenatide to basal insulin was studied because these medicines target separate components of HbA_{1c}, an important measure of blood glucose control. Lixisenatide has a pronounced PPG-lowering effect, which complements the predominantly fasting plasma glucose (FPG)-lowering effect of basal insulin. For patients treated with basal insulin who have controlled FPG but who, due to the progression of type 2 diabetes, are no longer able to achieve their HbA_{1c} goal, adding lixisenatide, which targets PPG, could be an effective strategy to achieve target glucose control.

Available data from the ongoing ELIXA trial, a cardiovascular outcome (CV) study of lixisenatide in patients at high CV risk (i.e. patients who recently experienced an acute coronary event) were also submitted, as required by the FDA.

Sanofi is preparing to launch lixisenatide in the European Union as of late Q1 2013 under the proprietary name Lyxumia. The proprietary name for lixisenatide in the United States is under consideration.

About lixisenatide

Lixisenatide 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.

Lixisenatide was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com, and is approved in Europe for the treatment of adults with type 2 diabetes mellitus to achieve glycemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycemic control. Lixisenatide is also approved in Mexico for the treatment of adults with type 2 diabetes.

About GetGoal

The 11 GetGoal clinical trials supporting the lixisenatide NDA filing studied the benefits and risks related to using lixisenatide as monotherapy, in combination with oral anti-diabetic medicines, in combination with basal insulin and versus twice-daily exenatide.

Monotherapy

GetGoal-Mono evaluated the efficacy, safety and tolerability of lixisenatide as monotherapy in comparison to placebo over 12 weeks of treatment.

GetGoal-Mono Japan evaluated the efficacy, safety and tolerability of lixisenatide as monotherapy in patients with type 2 diabetes in Japan over 76 weeks of treatment.

Add-on to oral anti-diabetic medicines

GetGoal-F1 evaluated the efficacy, safety and tolerability of lixisenatide in association with metformin in comparison to placebo over 24 weeks of treatment, followed by an extension period.

GetGoal-S evaluated the efficacy, safety and tolerability of lixisenatide in association with sulfonylurea with or without metformin in comparison to placebo over 24 weeks of treatment, followed by an extension period.

GetGoal-M evaluated the efficacy, safety and tolerability of lixisenatide in association with metformin in comparison to placebo over 24 weeks of treatment, followed by an extension period.

GetGoal-P evaluated the efficacy, safety and tolerability of lixisenatide in association with pioglitazone with or without metformin in comparison to placebo over 24 weeks of treatment, followed by an extension period.

GetGoal-M Asia assessed the effects of lixisenatide as an add-on treatment to metformin with or without sulfonylureas on glycemic control (in terms of HbA_{1c} reduction) in comparison to placebo over 24 weeks of treatment.

Add-on to basal insulin

GetGoal-L Asia evaluated the efficacy, safety and tolerability of lixisenatide in association with basal insulin with or without sulfonylurea in comparison to placebo over 24 weeks of treatment.

GetGoal-L evaluated the efficacy, safety and tolerability of lixisenatide in association with basal insulin with or without metformin in comparison to placebo over 24 weeks of treatment, followed by an extension period.

GetGoal-Duo1 assessed the effects of lixisenatide as an add-on treatment to insulin glargine and metformin on glycemic control in comparison to placebo over 24 weeks of treatment.

Versus twice-daily exenatide

GetGoal-X compared the efficacy, safety and tolerability of lixisenatide versus twice-daily exenatide in association with metformin over 24 weeks of treatment, followed by an extension period.

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.

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).

Forward-Looking Statements

This press release contains forward-looking statements. 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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