



Data Show Sanofi's Lyxumia[®] Added to Basal Insulin Lowered Blood Sugar Especially when Fasting Plasma Glucose was Controlled

- Findings Consistent with Known Post-Prandial Effect of Lyxumia Supporting Combination with Basal Insulin -

Paris, France – September 24, 2013 – Sanofi (EURONEXT : SAN and NYSE : SNY) announced today new GetGoal-L sub-analysis results showing that reductions in HbA_{1c} with Lyxumia[®] (lixisenatide), when added to basal insulin, were greatest in patients with type 2 diabetes who had well-controlled baseline fasting plasma glucose (FPG). These findings are consistent with the efficacy profile of Lyxumia, which shows a clinical and statistically significant reduction in HbA_{1c} across different patient populations.

The results also showed that reductions in body weight with Lyxumia, when added to basal insulin, were greatest in this group. The GetGoal-L sub-analysis was shared during an oral presentation at the 49th Annual Meeting of the European Association for the Study of Diabetes in Barcelona.

"The study showed that Lyxumia is an effective post-prandial glucose lowering option that improves HbA_{1c} levels when added to basal insulin," said Professor Josep Vidal, Endocrinology and Nutrition, University of Barcelona. *"We analyzed data from patients who were not at their target HbA_{1c} level, despite controlled fasting plasma glucose, and we found that a treatment regimen that targets post-prandial glucose, as well as fasting plasma glucose, could be an effective choice for these patients."*

As type 2 diabetes progresses over time, patients treated with basal insulin may no longer maintain their target HbA_{1c} level (average blood sugar levels over the past 2 to 3 months) despite typically sustaining good control of FPG with basal insulin. For these patients, Lyxumia can significantly reduce HbA_{1c} by primarily reducing post-prandial (after-meal) glucose levels through its complementary action with basal insulin. Targeting both FPG and post-prandial glucose could be an effective way to lower HbA_{1c} in certain patients with type 2 diabetes.

Results of Analysis

This sub-analysis examined 496 patients with type 2 diabetes and inadequate glucose control. Results showed that the addition of lixisenatide to basal insulin treatment, with or without metformin (oral anti-diabetic therapy), reduced overall HbA_{1c}, body weight and post-breakfast self-monitored post-prandial glucose in all groups. These effects were greater in patients with relatively well-controlled baseline FPG levels (below or equal to 6.7 mmol/L; FPG in people without diabetes is ~5.5 mmol/L¹) compared to those with higher baseline FPG levels (between 6.7 and 8.9 mmol/L, and over 8.9 mmol/L, respectively).

The GetGoal-L sub-analysis abstract is entitled: 'Therapeutic efficacy of lixisenatide added to basal insulin is greater when FPG is well-controlled' (Vidal J, et al. [Abstract no. oral presentation 6]).

About Lyxumia[®] (lixisenatide)

Lyxumia[®] (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.



Lyxumia 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. Lyxumia is also approved in Mexico, Australia, Japan and Brazil for the treatment of adults with type 2 diabetes. Sanofi plans to resubmit the New Drug Application for lixisenatide in the United States in 2015, after completion of the ELIXA cardiovascular outcomes study. Lyxumia is the proprietary name approved by the European Medicines Agency and other health authorities for the GLP-1 RA lixisenatide.

The Lyxumia pen is the winner of a number of innovative design awards, including the Red Dot Award, the Good Design Award, and the iF Product Design Award.

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 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. International Diabetes Federation. Global Guideline for Type 2 Diabetes (2012). Available at: www.idf.org/sites/default/files/IDF-Guideline-for-Type-2-Diabetes.pdf. Date accessed: September 2013.

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, 2012. 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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