



Sanofi Submits Application for Regulatory Approval for Lyxumia[®] (lixisenatide) for the Treatment of Type 2 Diabetes in Japan

Paris, France – June 11, 2012 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the marketing authorization application for Lyxumia[®] (lixisenatide), an investigational once-daily GLP-1 receptor agonist has been submitted for review to the Ministry of Health, Labour and Welfare in Japan.

The application is supported by data from the extensive international GetGoal Phase III clinical trial program, which has assessed lixisenatide's intended indication for the treatment of adults with type 2 diabetes with the aim of achieving glycemic control in patients who were not adequately controlled on diet & exercise with or without oral anti-diabetics and/or basal insulin. The GetGoal program has enrolled more than 5,000 participants, including subjects in Japan, and has studied the highest numbers of patients to evaluate a GLP-1 in combination with basal insulin¹.

The GetGoal program has established lixisenatide's good efficacy and safety profile, demonstrating a significant reduction in HbA_{1c}. As expected from a GLP-1 receptor agonist, lixisenatide was associated with a low risk of hypoglycemia, and in terms of tolerability, nausea and vomiting were the most commonly reported adverse events. Data for the regulatory submission includes positive results from the GetGoal-L Asia study² investigating the efficacy and safety of lixisenatide versus placebo in Asian patients with type 2 diabetes who were insufficiently controlled on basal insulin ± sulfonylurea on top of diet & exercise.

The submission to the Ministry of Health, Labour and Welfare follows the acknowledged receipt of the market authorization application filing for lixisenatide by the European Medicine Agency (EMA) in November 2011. Submission for regulatory approval of lixisenatide in the United States is expected in Q4 2012. The first set of results from the various studies of the GetGoal program have been published in peer reviewed medical journals, and others will be submitted for publication in the next few months.

About Lyxumia[®] (lixisenatide)

Lixisenatide, a glucagon-like peptide-1 agonist (GLP-1), is in development for the treatment of patients with type 2 diabetes mellitus. Lixisenatide was in-licensed from Zealand Pharma A/S (Copenhagen, Denmark), www.zealandpharma.com. Lyxumia[®] is the intended trademark of lixisenatide. Lixisenatide is not currently approved or licensed anywhere in the world.

GLP-1 is a naturally-occurring peptide that is released within minutes of eating a meal. It is known to suppress glucagon secretion from pancreatic alpha cells and stimulate insulin secretion by pancreatic beta cells. GLP-1 receptor agonists are in development as an add-on treatment for type 2 diabetes and their use is endorsed by the European Association for the Study of Diabetes, the American Diabetes Association, the American Association of Clinical Endocrinologists and the American College of Endocrinology.



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 and has enrolled more than 5,000 participants.

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 agonist being studied as a single agent, in combination with basal insulin, and/or in combination with oral antidiabetic 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/>. Date accessed: June 2012
2. Seino Y et al, *Diab Obes Metab.*, May 2012 (Epub ahead of print) date accessed 28/05/12

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 labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products 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 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, 2010. 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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