



Sanofi New Drug Application for Lixisenatide Accepted for Review by FDA

- First New Drug Application for a GLP-1 receptor agonist to include CV outcomes data -

Paris, France - September 29th, 2015 - [Sanofi](#) announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for lixisenatide, an investigational once-daily prandial GLP-1 receptor agonist for the treatment of adults with type 2 diabetes mellitus (T2DM).

“The FDA filing notification for lixisenatide is an important milestone for Sanofi,” said Pierre Chancel, Senior Vice President, Head of Global Diabetes at Sanofi. *“Sanofi’s integrated portfolio of marketed products provides treatment, monitoring and support at every stage of the diabetes journey. Lixisenatide is a critical element of this portfolio, and we look forward to working with the FDA during the review process with the goal of bringing lixisenatide to patients in the U.S.”*

The NDA submission for lixisenatide is based on results from the GetGoal clinical program^{1,2} and includes findings from the recently-completed ELIXA study,³ the first completed long-term CV outcomes study of a GLP-1 receptor agonist. The GetGoal Phase III clinical program enrolled more than 5,000 patients worldwide, evaluating the safety and efficacy of lixisenatide, including its treatment effect on HbA_{1c}, post-prandial glucose and body weight in adults with T2DM. The ELIXA trial evaluated the cardiovascular safety of lixisenatide versus standard of care in more than 6,000 adults with T2DM and high CV risk (i.e., patients who have recently experienced a spontaneous acute coronary syndrome event).

The proprietary name for lixisenatide in the United States is under consideration. Lyxumia[®] is the proprietary name approved by the European Medicines Agency and other health authorities.

About Lixisenatide

Lixisenatide is a once-daily prandial glucagon-like peptide-1 receptor agonist (GLP-1 RA) for the treatment of adult 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 was approved in Europe in 2013 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 currently approved in over 60 countries worldwide for the treatment of adults with type 2 diabetes, with commercial launches in most EU countries, Japan, Brazil, Mexico and other markets. Lixisenatide is an investigational product in the U.S.

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 injectable, inhaled and oral medications for people with type 1 or type 2 diabetes.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: [SAN](#)) and in New York (NYSE: [SNY](#)).

References

1. Bain SC. Diabetes Therapy 2014 5(2): 367-383, DOI 10.1007/s13300-014-0073-z.
2. Rosenstock J, et al. Abstract 107-LB presented at ADA 75th Scientific Sessions, Boston, U.S., 2015. Date accessed: June 2015. (GetGoal Duo 2).
3. Pfeffer MA, et al. Symposium - The Evaluation of Lixisenatide in Acute Coronary Syndrome—The Results of ELIXA. Presented at ADA 75th Scientific Sessions, Boston, U.S., 2015.

Sanofi 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, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Contacts:

Media Relations

Jack Cox
Tel.: + (33) 1 53 77 46 46
mr@sanofi.com

Global Diabetes Communications

Philip McNamara
Tel.: +1 908 981 5497
philip.mcnamara@sanofi.com

Investor Relations

Sébastien Martel
Tel.: + (33) 1 53 77 45 45
ir@sanofi.com

U.S. Diabetes Communications

Susan Brooks
Office: +1 908 981 6566
susan.brooks@sanofi.com