



Sanofi's Lyxumia[®] (lixisenatide) Demonstrated Cardiovascular Safety in People with Type 2 Diabetes and High CV Risk

- *ELIXA is the first event-driven cardiovascular outcomes study to provide data for a GLP-1 receptor agonist* -

- *Full results for ELIXA study presented at American Diabetes Association's 75th Scientific Sessions* -

Paris, France - June 8, 2015 - [Sanofi](#) announced today the presentation of full results of the Phase IIIb ELIXA study, which was designed to assess the cardiovascular (CV) safety of Lyxumia[®] (lixisenatide) in adults with type 2 diabetes and high CV risk. As previously reported, lixisenatide met the pre-specified criterion of non-inferiority versus placebo for the composite primary endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke and hospitalization for unstable angina but did not demonstrate superiority. The full results will be included in the U.S. New Drug Application for lixisenatide, which is on track to be resubmitted to the U.S. Food and Drug Administration in Q3 2015.

Additional safety findings include no signal for increased risk of heart failure, pancreatitis, pancreatic cancer or severe symptomatic hypoglycemia. Lixisenatide was generally safe and well tolerated; nausea and vomiting, which are known side effects of the GLP-1 RA class, were observed more frequently with lixisenatide.

"The importance of determining the CV safety of diabetes medicines, as set out in the FDA guidance issued in 2008, is widely recognized. People around the world are being treated with GLP-1 receptor agonists, and the CV effects were unknown," said Dr. Marc Pfeffer, Professor of Medicine at Harvard Medical School, Senior Physician in the Division of Cardiovascular Medicine at Brigham and Women's Hospital and Chair of the ELIXA Steering Committee. *"ELIXA goes beyond the FDA guidance to deliver data related to heart failure and other insights that are not currently available for any other GLP-1 receptor agonist. Our data provide the medical community, patients and caregivers with information that will better inform them about how lixisenatide can be safely used to better control their glucose."*

"As the first completed long-term CV safety study of a GLP-1 receptor agonist, the successful ELIXA trial will be shared with health authorities around the world and provides important outcomes data that can be considered by healthcare professionals," said Pierre Chancel, Senior Vice President, Head of Global Diabetes at Sanofi. *"Sanofi is committed to developing and delivering safe and effective treatment options for people with diabetes. This study supports that important work."*

Full study results were presented today during a symposium at the American Diabetes Association 75th Scientific Sessions in Boston.

Results of Analysis

Lixisenatide met the pre-specified criterion of non-inferiority versus placebo for the composite primary endpoint of MACE[†]: CV death, non-fatal myocardial infarction, non-fatal stroke and hospitalization for unstable angina (Hazard Ratio [95% CI]: 1.017 [0.886 to 1.168]). Since the upper bound of the 95% CI was greater than 1.0, superiority over placebo in reducing the composite primary endpoint was not met.



The CV safety of lixisenatide was also confirmed by further analyses (e.g. MACE Hazard Ratio [95% CI]: 1.02 [0.887 to 1.172]). No signal for increased risk of heart failure (HF) was observed (Hazard Ratio [95% CI]: 0.96 [0.75 to 1.23]).

Measures of non-CV safety showed pancreatitis (0.2% with lixisenatide and 0.3% with placebo), pancreatic cancer (<0.1% with lixisenatide and 0.3% with placebo), severe symptomatic hypoglycemia (0.3 events per 100 patient-years with lixisenatide; 0.6 per 100 patient-years with placebo), malignancy (2.9% with lixisenatide and 2.6% with placebo), drug-related allergic reactions (0.2% with both lixisenatide and placebo).

Conference Call on Diabetes for the Financial Community

Sanofi will host an IR Thematic Conference Call on Diabetes for the financial community in connection with the upcoming American Diabetes Association's Scientific Sessions.

The call/webcast will take place on Tuesday June 9th, 2015 at:
2 pm Paris (CEST) / 1 pm London (BST) / 8 am New York (EDT) / 5 am San Francisco (PDT)

The conference call will include a presentation followed by a Q&A session. It will be accessible through audio webcast at www.sanofi.com and via the following telephone numbers:

- France +33 (0) 1 70 77 09 40
- UK +44 (0) 203 367 9453
- US +1 866 907 59 28

REPLAY NUMBERS

- France +33 (0) 1 72 00 15 00
- UK +44 (0) 203 367 9460
- US +1 877 64 230 18

CONFERENCE CODE 293697#

About ELIXA

ELIXA (Evaluation of Cardiovascular Outcomes in Patients With Type 2 Diabetes After Acute Coronary Syndrome During Treatment With Lixisenatide) is the first event-driven cardiovascular outcomes study to provide data for a glucagon-like peptide-1 receptor agonist (GLP-1 RA). ELIXA was a randomized, double-blind, parallel group trial designed to evaluate cardiovascular risk, comparing lixisenatide to placebo in a high-risk population of adults with type 2 diabetes. More than 6,000 adults with type 2 diabetes and high CV risk (i.e., patients who have recently experienced a spontaneous acute coronary syndrome event) participated in the trial. The composite primary endpoint, which was evaluated for non-inferiority and superiority, comprised cardiovascular (CV) death, non-fatal myocardial infarction, non-fatal stroke, or hospitalization for unstable angina. The global ELIXA study started in June 2010 and was completed in 2015.

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 50 countries worldwide for the



treatment of adults with type 2 diabetes, with commercial launches in most EU countries, Japan, Brazil, Mexico and other markets. Lyxumia is the proprietary name approved by the European Medicines Agency and other health authorities for the GLP-1 RA lixisenatide. Lixisenatide is an investigational product in the U.S. It will be resubmitted to the Food & Drug Administration (FDA) in the third quarter of 2015. The proprietary name in the U.S. is under consideration.

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](#)).

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.

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