



Sanofi Announces Top-Line Results for Cardiovascular Outcomes Study of Lyxumia® (lixisenatide)

- Results support resubmission of U.S. New Drug Application in Q3 2015 -

Paris, France – March 19, 2015 - [Sanofi](#) announced today top-line results of the Phase IIIb ELIXA cardiovascular outcomes study, which compared lixisenatide to placebo in a high-risk population of adults with type 2 diabetes evaluating cardiovascular safety. The study showed that lixisenatide was non-inferior, although not superior, to placebo for cardiovascular safety.

ELIXA full results will be presented Monday, June 8, 2015, at the American Diabetes Association 75th Scientific Sessions in Boston by the ELIXA steering committee, chaired by Dr. Marc Pfeffer. The results will also be included in the U.S. New Drug Application of lixisenatide, which is on track to be resubmitted to the U.S. Food and Drug Administration in the third-quarter of 2015. Lixisenatide is not approved in the United States.

“The completion of the ELIXA study is a significant milestone for lixisenatide, which is the first GLP-1 receptor agonist with long-term cardiovascular safety data in people with diabetes who have high cardiovascular risk,” said Dr. Elias Zerhouni, President, Global R&D at Sanofi. *“Sanofi looks forward to submitting the results to health authorities worldwide.”*

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 some European 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. 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 the field of healthcare with seven growth platforms: 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.

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 (0) 908 981 6566
Mobile: +1 (0) 201 572 49 94
susan.brooks@sanofi.com