Sanofi Provides Update on Lixisenatide New Drug Application in U.S.

Paris, France – September 12, 2013 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today its decision to withdraw the lixisenatide New Drug Application (NDA) in the U.S., which included early interim results from the ongoing ELIXA cardiovascular (CV) outcomes study. The company plans to resubmit the NDA in 2015, after completion of the ELIXA CV study.

The decision to withdraw the lixisenatide application follows discussions with the U.S. Food and Drug Administration (FDA) regarding its proposed process for the review of interim data. Sanofi believes that potential public disclosure of early interim data, even with safeguards, could potentially compromise the integrity of the ongoing ELIXA study. Sanofi's decision is not related to safety issues or deficiencies in the NDA.

The ELIXA study continues as planned and is fully enrolled. Complete results should be available in approximately 15 months. Therefore, Sanofi came to the conclusion that the most appropriate option is to support the FDA's evaluation of lixisenatide based on the complete results of the ELIXA study rather than interim data.

The combination of lixisenatide and Lantus® (basal insulin), the investigational LixiLan fixed-ratio product, remains on schedule to enter into phase 3 in the first half of 2014.

Sanofi looks forward to working with the FDA in the future to resubmit the lixisenatide NDA.

About ELIXA Study

The **E**valuation of **LIX**isenatide in **A**cute coronary syndrome (ELIXA) study is an ongoing event-driven cardiovascular (CV) outcomes study in patients with high CV risk (i.e., patients who recently experienced an acute coronary event.) The global ELIXA study started in June 2010. The target enrollment was 6,000 patients and, as of August 2013, the study is fully enrolled. Complete results should be available in approximately 15 months.

About lixisenatide

Lixisenatide 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. Lixisenatide is also approved in Mexico, Australia and Japan for the treatment of adults with type 2 diabetes. Lyxumia is the proprietary name approved by the European Medicines Agency and other health authorities for lixisenatide.

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.

Lixisenatide was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com.

About Sanofi

Sanofi, an integrated 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 the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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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