FDA Advisory Committee Recommends Approval of Sanofi Treatment for Adults with Type 2 Diabetes

- FDA decisions on the investigational fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide and investigational lixisenatide anticipated in Q3 2016 -

Paris, France - May 25, 2016 - Sanofi announced today that the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the U.S. Food and Drug Administration (FDA) recommended the approval of the New Drug Application (NDA) for the investigational fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide for the treatment of adults with type 2 diabetes. The 15-member panel voted 12 to 2 (1 panelist did not vote due to travel) to approve the fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide.

"We are pleased by the Advisory Committee's recommendation for approval of this investigational diabetes therapy," said Elias Zerhouni, President, Global R&D, Sanofi. *"By combining the complementary therapeutic effects of insulin glargine on fasting plasma glucose and of lixisenatide on postprandial plasma glucose, both of which can contribute to HbA1c lowering, this fixed-ratio product may address some of the unmet needs of adults living with type 2 diabetes who are considering initiating or intensifying insulin. We look forward to continuing to work with the FDA as it completes its reviews of these New Drug Applications."*

The NDA submission for the fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide is based on data from two Phase 3 studies, which enrolled more than 1,900 adults worldwide to evaluate the efficacy and safety of the fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide when used in patient populations insufficiently controlled after oral antidiabetic agents (OADs) and after basal insulin therapy, respectively. Both studies met their primary endpoints. The full results of both studies will be presented in June 2016 at the American Diabetes Association's 76th Scientific Sessions.

The NDA submission for lixisenatide is based on results from the GetGoal clinical program, which included 13 clinical trials involving more than 5,000 adults with type 2 diabetes. The NDA submission for lixisenatide also includes findings from the ELIXA study, a long-term cardiovascular (CV) outcomes study in adults with type 2 diabetes and high CV risk (i.e., patients who have recently experienced a spontaneous acute coronary syndrome event).

Lixisenatide and the fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide are undergoing FDA review, with decisions anticipated in July and August 2016, respectively. The proprietary names for both compounds in the U.S. are under consideration. Lixisenatide is currently approved in more than 60 countries worldwide under the proprietary name Lyxumia®. The fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide was submitted for regulatory review in the European Union in March 2016 and has not yet been approved for use by any health authority.

About Sanofi Diabetes & Cardiovascular

Diabetes and cardiovascular disease affect millions of people worldwide, with many managing the complex challenges of both. Building on our portfolio evolution, heritage and expertise, Sanofi has a

focused business unit dedicated to delivering innovative, value-based medicines and integrated solutions in these therapeutic areas. We are committed to a collaborative approach that involves strategic alliances with professional and patient associations, research institutions and leaders in healthcare and other industries, with the goal of advancing scientific knowledge, driving the convergence of science and technology, helping to improve outcomes and inspiring an evolution in care.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial. 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 initiatives 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, 2015. 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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