FDA Accepts Sanofi New Drug Application for Once-Daily Fixed-Ratio Combination of Insulin Glargine and Lixisenatide

- FDA decision anticipated in August 2016 -

- Regulatory submission based on results from Phase 3 clinical trial program in adults with type 2 diabetes -

Paris, France – February 22, 2016 - Sanofi announced today that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for its 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.

Following the redemption of a Priority Review Voucher with the submission, an FDA decision is anticipated in August 2016.

"The FDA filing notification is an important milestone for Sanofi as we work to broaden our diabetes portfolio," said Pascale Witz, Executive Vice President, Global Diabetes & Cardiovascular, Sanofi. "*Physicians may need to consider fasting and mealtime blood glucose imbalances in their overall management of diabetes, and additional treatment options are needed. We look forward to working with the FDA during the review process with a view toward bringing this investigational medicine to adults with type 2 diabetes in the U.S."*

This NDA submission is based on data from two Phase 3 studies, which enrolled more than 1,900 patients worldwide to evaluate the safety and efficacy of the fixed-ratio combination when used in patient populations insufficiently controlled after oral antidiabetic agents (OADs) and after basal insulin therapy, respectively. Both studies met their primary endpoints and will be presented at a medical congress in 2016.

The safety and efficacy of the fixed-ratio combination have not been evaluated by any regulatory authority, and the proprietary name is under consideration. Preparations are on track for regulatory submission in the European Union in March 2016. The investigational GLP-1 receptor agonist lixisenatide was evaluated in patients with type 2 diabetes and is also currently under review by the FDA. The NDA for lixisenatide was accepted in September 2015, and an FDA decision is anticipated in July 2016.

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 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, 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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