



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

Paris, France – December 23, 2015 - [Sanofi](#) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its investigational fixed-ratio combination of insulin glargine 100 Units/mL and lixisenatide, which if approved would be administered as a single daily injection for the treatment of adults with type 2 diabetes.

“This NDA submission is a significant milestone in Sanofi’s efforts to further develop our insulin franchise,” said Pierre Chancel, Senior Vice President, Head of Global Diabetes at Sanofi. *“A large unmet medical need still exists for people with type 2 diabetes, as more than half are not at their blood sugar goal despite using oral medications or insulin. We recognize the need for additional treatment options and look forward to working with the FDA during their consideration of our submission.”*

Sanofi redeemed a priority review voucher (PRV) with the submission to designate the NDA for an expedited 6-month review if the submission is accepted by the FDA, instead of the standard 10-month review.

This NDA submission is based on data from the LixiLan-O and LixiLan-L Phase III studies, which both reported positive top-line results earlier in 2015. These studies enrolled more than 1,900 patients worldwide to evaluate the safety and efficacy of the fixed-ratio combination when used in patient populations uncontrolled after oral antidiabetic agents (OADs) and after basal insulin therapy, respectively.

The proprietary name for the fixed-ratio combination is under consideration. Its safety and efficacy have not been evaluated by any regulatory authority.

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.

Contacts:

Media Relations

Jack Cox

Tel.: + (33) 1 53 77 46 46

mr@sanofi.com

Investor Relations

Sébastien Martel

Tel.: + (33) 1 53 77 45 45

ir@sanofi.com

Global Diabetes Communications

Philip McNamara

Tel.: +1 908 981 5497

philip.mcnamara@sanofi.com

U.S. Diabetes Communications

Susan Brooks

Tel: +1 908 981 6566

susan.brooks@sanofi.com