Sanofi Receives CHMP Recommendation for Approval of Suliqua™ in the EU

Paris, France – November 11, 2016 – Sanofi announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for the marketing authorization of Suliqua™, the once-daily titratable fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide. CHMP recommended the use of Suliqua for the treatment of adults with type 2 diabetes mellitus to improve glycemic control in combination with metformin when metformin alone or combined with another oral antidiabetic agent (OAD) or with basal insulin do not provide adequate glycemic control.

"We welcome the CHMP positive opinion for Suliqua and look forward to the final decision of the European Commission (EC), as well as the upcoming U.S. Food and Drug Administration decision," said Elias Zerhouni, M.D., President, Global R&D, Sanofi. *"Today's opinion brings us one step closer to delivering in Europe this important and innovative treatment option, which combines two widely used and complementary medicines into a single daily injection that we feel will benefit people with type 2 diabetes who are struggling to keep their blood sugar levels under control."*

The CHMP positive opinion is based on data from two Phase 3 studies, LixiLan-O and LixiLan–L, which enrolled more than 1,900 adults with type 2 diabetes worldwide to evaluate the efficacy and safety of the fixed-ratio combination when used in patient populations insufficiently controlled after OADs and after basal insulin therapy, respectively. Both studies met their primary endpoints, demonstrating statistically superior HbA1c reduction versus lixisenatide and insulin glargine 100 Units/mL in LixiLan-O,[1] and versus insulin glargine 100 Units/mL in LixiLan-L.[2]

Suliqua is the brand name in Europe for the once-daily titratable fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide. The European Commission is expected to make a final decision on marketing authorization for Suliqua in the coming months. The fixed-ratio combination is currently under review in a total of nine markets, including the United States, where a U.S. Food and Drug Administration decision is anticipated later this month.

Once approved, Suliqua will be available in the EU in two pre-filled SoloStar® pens, providing different dosing options that will help answer individual market and patient needs. The differentiation between the pen strengths is based on the dose range of each pen. The 10–40 SoloStar pre-filled pen will deliver 10 to 40 dose steps of insulin glargine in combination with 5 to 20 micrograms of lixisenatide. The 30–60 SoloStar pre-filled pen will deliver 30 to 60 dose steps of insulin glargine in combination with 10 to 20 micrograms of lixisenatide.

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 regarding the clinical development of and potential marketing approvals for Suliqua. Forward-looking statements are generally identified by the

words "expects", "anticipates", "believes", "intends", "estimates", "plans", "will be" 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 of Suliqua, 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 Suliqua as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of Suliqua, the absence of guarantee that Suliqua if approved will be commercially successful, risks associated with intellectual property, future litigation, the future approval and commercial success of therapeutic alternatives, and volatile economic conditions, as well as those risks 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.

Contacts:

Media Relations
Mai Tran
Tel.: + (33) 1 53 77 46 46
mr@sanofi.com

Investor Relations
George Grofik
Tel.: + (33) 1 53 77 45 45
ir@sanofi.com

Global Diabetes Communications
Philip McNamara
Tel.: +1 908 938 0390
philipmcnamara@sanofi.com

References

1. Rosenstock J, et al. Diabetes Care. 2016, Online ahead of print, DOI: 10.2337/dc16-0917.
2. Aroda VR, et al. Diabetes Care. 2016, Online ahead of print, DOI: 10.2337/dc16-1495.