Suliqua™ Approved in the European Union for the Treatment of Adults with Type 2 Diabetes

Paris, France - January 18th , 2017 - Sanofi announced today that the European Commission has granted marketing authorization in Europe for Suliqua™, the once-daily titratable 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. Suliqua is authorized for use in combination with metformin to improve glycemic control when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product or with basal insulin.[1]

"Suliqua is an innovative new combination therapy that has the potential to address significant unmet needs for people living with type 2 diabetes in Europe," said Elias Zerhouni, M.D., President, Global R&D, Sanofi. *"The approval of Suliqua represents the successful culmination of a concerted effort by Sanofi scientists to bring two injectable treatments together in a single and precisely titratable dose. Sanofi has a long history of elevating care for people with diabetes, and we believe Suliqua will make it easier for patients with inadequately controlled diabetes to reach their treatment goals."*

The decision to grant marketing authorization in Europe for Suliqua was 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. Suliqua demonstrated statistically superior blood sugar (HbA_{1c}) reduction versus lixisenatide (-0.8%, $p<0.0001$) and insulin glargine 100 Units/mL (-0.3%, $p<0.0001$) in LixiLan-O, and versus insulin glargine 100 Units/mL (-0.5%, $p<0.0001$) in LixiLan-L.[2,3]

Suliqua will be delivered in two pre-filled SoloSTAR® pens, providing different dosing options that may help answer individual market and patient insulin needs. The differentiation between the pen strengths is based on the dose range and ratios of each pen. The 10–40 SoloSTAR pre-filled pen will deliver 10 to 40 dose steps of insulin glargine 100 Units/mL 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 100 Units/mL in combination with 10 to 20 micrograms of lixisenatide.[1]

"We welcome the addition of Suliqua in the EU to help address the needs of people living with type 2 diabetes who are currently not reaching their blood sugar targets," said Javier Ampudia Blasco, Specialist of Endocrinology and Nutrition at the Clinic University Hospital Valencia and Associate Professor of Medicine at the Medicine Faculty of Valencia in Spain. *"It is important to achieve glycemic control without increasing the risk of hypoglycemic events or additional weight gain when oral agents or basal insulin are no longer sufficient. The simple administration of this combination product of insulin and a glucagon-like peptide-1 receptor agonist in a single daily injection may help to reduce the daily complexity of diabetes management and improve efficacy for people with type 2 diabetes compared with its components. Suliqua is easy to use with dose adjustments based only in the fasting glucose values."*

Marketing authorization in Europe for Suliqua is applicable to the 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway, and follows the November 2016 positive

opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The product was approved by the U.S. Food and Drug Administration (FDA) in November 2016, as Soliqua™ 100/33, and has been available in the U.S. since January 4, 2017. Launches in individual EU countries are anticipated from Q2 2017 onward.

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 Consumer Healthcare. 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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans", "looks forward" 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, 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.

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1. Suliqua™ EU Summary of Product Characteristics, 2017.
2. Rosenstock J, et al. Diabetes Care. 2016, DOI: 10.2337/dc16-0917.
3. Aroda VR, et al. Diabetes Care. 2016, DOI: 10.2337/dc16-1495.