Sanofi's Fixed-Ratio Combination Helps More Patients Reach Mealtime Blood Sugar Target than Insulin Glargine Alone

– Titratable fixed-ratio combination of insulin glargine and lixisenatide demonstrates better post-prandial glycemic control in adults with type 2 diabetes –

Paris, France – September 13, 2016 - Sanofi announced today that iGlarLixi, the investigational, titratable fixed-ratio combination of insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide*, offers greater control of mealtime blood sugar (post-prandial glucose, PPG) in adults living with type 2 diabetes compared to insulin glargine 100 Units/mL alone. A new post-hoc analysis of data from the LixiLan-L pivotal Phase III clinical trial found more patients who received the fixed-ratio combination reached their daily PPG target than those who received only insulin glargine 100 Units/mL. The new analysis was presented at the European Association for the Study of Diabetes (EASD) 52nd Annual Meeting in Munich, Germany. iGlarLixi is currently under review in the United States and Europe.

"Controlling mealtime blood sugar is an important element of maintaining overall blood sugar control, which plays a role in helping patients treat their diabetes," said Josep Vidal, Hospital Clinic of Barcelona, Barcelona, Spain, and lead author of the study. *"This new analysis provides further evidence supporting the use of iGlarLixi by adults with type 2 diabetes who need mealtime blood sugar control alongside greater control of their HbA1c."*

The analysis also showed that a significantly higher proportion of participants reached their PPG target after 30 weeks, according to self-measured plasma glucose (SMPG) taken at intervals throughout the day. As previously reported for LixiLan-L, incidence of symptomatic hypoglycemia was similar with the titratable fixed-ratio combination and insulin glargine 100 Units/mL.

"In the LixiLan-L pivotal Phase III clinical trial, investigational iGlarLixi demonstrated superior HbA1c reduction compared with insulin glargine 100 Units/mL alone," said Riccardo Perfetti, Head of Global Diabetes Medical Team, Sanofi. *"With this new analysis, we see further evidence of the role iGlarLixi can serve in helping type 2 diabetes patients meet their PPG targets."*

The presentation abstract is titled **'Post-Prandial Glycemic Outcomes of a Fixed Ratio Combination of Insulin Glargine and Lixisenatide in the LixiLan-L Trial (NCT02058147)'** (Vidal, J et al. Poster presentation 801 – EASD 52nd Annual Meeting in Munich, Germany at 13:15 p.m. CET on September 13)

Summary of Results

The post-hoc analysis reviewed data from the LixiLan-L pivotal Phase III trial, which compared the effectiveness of the two treatments in 736 adults whose type 2 diabetes was not adequately controlled at screening on insulin glargine alone or combined with one or two oral anti-diabetic agents. The primary outcome of the LixiLan-L study, a statistically significant reduction in HbA1c (average blood glucose over the previous three months) compared with insulin glargine 100 Units/mL, was previously reported at the American Diabetes Association 76th Scientific Sessions, 2016.

In the 677 participants included in the post-hoc analysis with standardized meal test data at baseline and week 30, the fixed-ratio combination demonstrated greater PPG control compared with insulin glargine 100 Units/mL. The percentage of patients achieving PPG ≤7.8 mmol/L at Week 30 was greater in the fixed-ratio combination group versus the insulin glargine 100 Units/mL group at 0.5 hour (difference: 16.4% [41.4% vs. 25%], p<0.0001); one hour (difference: 22.4% [30.7% vs. 8.3%], p<0.0001) and two hour (difference: 28.2% [33.6% vs. 5.4%], p<0.0001) after a standardized liquid meal.

The fixed-ratio combination also demonstrated greater PPG control compared with insulin glargine 100 Units/mL in the 592 participants included in the post-hoc analysis with 7-point self-measured plasma glucose (SMPG) data at baseline and week 30. Consistently, more patients reached PPG targets after all meals throughout the day. The percentage of patients achieving PPG ≤7.8 mmol/L in a 7-point SMPG test at Week 30 was greater in the fixed-ratio combination group versus the insulin glargine 100 Units/mL group at 10 a.m. (difference: 32.5% [61.2% vs. 28.7%], p<0.0001); 3 p.m. (difference: 16.5% [41.1% vs. 24.6%], p<0.0001) and 10 p.m. (difference: 12.2% [45.9% vs. 33.7%], p=0.005).

As previously reported for LixiLan-L, documented (≤70 mg/dL /3.9 mmol/L) incidence of symptomatic hypoglycemia was similar with the titratable fixed-ratio combination (40% of patients; 3.0 events/year; E/Y) and insulin glargine 100 Units/mL (42.5% of patients; 4.2 E/Y). With the titratable fixed-ratio combination, 10.4% of participants experienced nausea, and 3.6% experienced vomiting; while with insulin glargine 100 Units/mL 0.5% of participants experienced nausea and 0.5% experienced vomiting.

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, Sanofi's ability to benefit from external growth opportunities, and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic

conditions, 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.

*Lixisenatide was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com

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