Sanofi Announces Positive Phase 3 Results for Investigational Titratable Fixed-Ratio Combination of Insulin Glargine and Lixisenatide

- Both pivotal studies demonstrated superior reduction in HbA1c versus insulin glargine and versus lixisenatide -

Paris, France - June 12, 2016 - Sanofi announced today the presentation of the results of the pivotal Phase 3 LixiLan-O and LixiLan-L clinical trials with the investigational titratable fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide in adults with type 2 diabetes. Both studies met their primary endpoints, demonstrating statistically superior reduction of HbA1c (average blood glucose over the previous three months) with the titratable fixed-ratio combination versus comparators (lixisenatide and insulin glargine 100 Units/mL, respectively). The most frequent adverse events were nausea, vomiting and diarrhea.

Full results were presented on June 12 at the American Diabetes Association 76th Scientific Sessions in New Orleans, LA, U.S. Top-line results were previously reported in Q3 of 2015.

"These studies reflect Sanofi's commitment to innovative approaches in developing medicines intended to help patients meet their needs throughout their diabetes journey," said Jorge Insuasty MD, Senior Vice President, Global Head of Development, Sanofi. *"We look forward to continuing to work with the FDA and EMA as they complete their reviews and to receiving their decisions."*

The results of the LixiLan-O and LixiLan-L studies have been included in regulatory submissions to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), with regulatory decisions anticipated in August 2016 (FDA) and Q1 2017 (EMA).

The presentation abstracts are titled:

- **Clinical Impact of Titratable Fixed-Ratio Combination of Insulin Glargine/Lixisenatide vs. Each Component Alone in Type 2 Diabetes Inadequately Controlled on Oral Agents: LixiLan-O Trial (NCT02058147)** (Rosenstock, J et al. Oral presentation 186-O, American Diabetes Association 76th Scientific Sessions, New Orleans, LA, U.S. at 8:45 a.m. on June 12, 2016).
- **Efficacy and Safety of the Insulin Glargine/Lixisenatide Fixed-Ratio Combination vs. Insulin Glargine in Patients with T2DM: the LixiLan-L Trial (NCT02058160)** (Aroda, V et al. Oral presentation 238-O, American Diabetes Association 76th Scientific Sessions, New Orleans, LA, U.S. at 2:30 p.m. on June 12, 2016).

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

Results of Analyses

LixiLan-O

LixiLan-O investigated the efficacy and safety of a once-daily single injection of the titratable fixed-ratio combination of insulin glargine 100 Units/mL and lixisenatide versus treatment with either lixisenatide or insulin glargine 100 Units/mL alone over a 30 week period in 1,170 patients whose type 2 diabetes was not adequately controlled on metformin alone or on metformin combined with a

second oral anti-diabetic agent. Treatment with metformin was continued for all participants throughout the study while other oral agents were discontinued.

After 30 weeks, the titratable fixed-ratio combination showed significantly greater reductions in HbA1c from baseline (8.1%) versus insulin glargine 100 Units/mL and lixisenatide (-1.6%, -1.3%, -0.9%, respectively; p<0.0001), reaching mean HbA1c levels of 6.5%, 6.8%, 7.3%, respectively. More subjects reached target HbA1c <7% with the titratable fixed-ratio combination (74%) versus insulin glargine 100 Units/mL (59%) or lixisenatide (33%). Mean body weight increased with insulin glargine 100 Units/mL (+1.1kg), and decreased with the titratable fixed-ratio combination (-0.3kg; difference 1.4kg, p<0.0001) and lixisenatide (-2.3kg).

Documented (≤70 mg/dL) symptomatic hypoglycemia was similar with the titratable fixed-ratio combination (25.6% of patients; 1.44 events/year; E/Y) and insulin glargine 100 Units/mL (23.6% of patients; 1.22 E/Y), but lower with lixisenatide (6.4% of patients; 0.34 E/Y). With the titratable fixed-ratio combination, 9.6% of participants experienced nausea and 3.2% experienced vomiting; with insulin glargine 100 Units/mL, 3.6% of participants experienced nausea and 1.5% experienced vomiting; and with lixisenatide 24.0% of participants experienced nausea and 6.4% experienced vomiting.

LixiLan-L

LixiLan-L investigated the efficacy and safety of the titratable fixed-ratio combination of insulin glargine 100 Units/mL and lixisenatide versus treatment with insulin glargine 100 Units/mL over a 30 week period in 736 patients whose type 2 diabetes was not adequately controlled at screening on basal insulin, alone or combined with one to two oral anti-diabetic agents. Treatment with metformin, if previously taken, was continued throughout the study while other oral agents were discontinued.

After 30 weeks, the titratable fixed-ratio combination showed significantly greater reductions in HbA1c from baseline (8.1%) versus insulin glargine 100 Units/mL (-1.1% versus -0.6%; p<0.0001), reaching mean HbA1c levels of 6.9% and 7.5%, respectively. More subjects reached target HbA1c <7% with the titratable fixed-ratio combination (55%) versus insulin glargine 100 Units/mL (30%; p<0.0001). Mean body weight increased with insulin glargine 100 Units/mL (+0.7 kg), and decreased with the titratable fixed-ratio combination (-0.7 kg; difference 1.4 kg, p<0.0001).

Documented (≤70 mg/dL) 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.

What is Lantus® (insulin glargine injection) 100 Units/mL?

Prescription Lantus is a long-acting insulin used to treat adults with type 2 diabetes and adults and pediatric patients (children 6 years and older) with type 1 diabetes for the control of high blood sugar.

- Do not use Lantus to treat diabetic ketoacidosis.

Important Safety Information For Lantus (insulin glargine injection) 100 Units/mL

Do not take Lantus during episodes of low blood sugar or if you are allergic to insulin or any of the inactive ingredients in Lantus.

Do not share needles, insulin pens, or syringes with others. Do NOT reuse needles.

Before starting Lantus, tell your doctor about all your medical conditions, including if you have liver or kidney problems, if you are pregnant or planning to become pregnant or if you are breast-feeding or planning to breast-feed.

Heart failure can occur if you are taking insulin together with certain medicines called TZDs (thiazolidinediones), even if you have never had heart failure or other heart problems. If you already have heart failure, it may get worse while you take TZDs with Lantus. Your treatment with TZDs and Lantus may need to be changed or stopped by your doctor if you have new or worsening heart failure. Tell your doctor if you have any new or worsening symptoms of heart failure, including:

- Shortness of breath
- Swelling of your ankles or feet
- Sudden weight gain

Tell your doctor about all the medications you take, including OTC medicines, vitamins, and supplements, including herbal supplements.

Lantus should be taken once a day at the same time every day. Test your blood sugar levels while using insulin, such as Lantus. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made cautiously and only under medical supervision.

Do NOT dilute or mix Lantus with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. Lantus must only be used if the solution is clear and colorless with no particles visible. Always make sure you have the correct insulin before each injection.

While using Lantus, do not drive or operate heavy machinery until you know how Lantus affects you. You should not drink alcohol or use other medicines that contain alcohol.

The most common side effect of insulin, including Lantus, is low blood sugar (hypoglycemia), which may be serious and life threatening. It may cause harm to your heart or brain. Symptoms of serious low blood sugar may include shaking, sweating, fast heartbeat, and blurred vision.

Lantus may cause serious side effects that can lead to death, such as severe allergic reactions. Get medical help right away if you have:

- A rash over your whole body
- Trouble breathing
- A fast heartbeat
- Sweating
- Swelling of your face, tongue, or throat
- Shortness of breath
- Extreme drowsiness, dizziness, or confusion

Other possible side effects may include swelling, weight gain, low potassium levels, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions.

Please see accompanying full prescribing information for Lantus or visit www.Lantus.com.

About Lixisenatide

Lixisenatide is a once-daily prandial glucagon-like peptide-1 receptor agonist (GLP-1 RA) for the treatment of adult patients with type 2 diabetes mellitus. GLP-1 is a naturally-occurring peptide hormone that is released within minutes after eating a meal. It is known to suppress glucagon secretion from pancreatic alpha cells and stimulate glucose-dependent insulin secretion by pancreatic beta cells.

Lixisenatide was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com, and was approved in Europe in 2013 for the treatment of adults with type 2 diabetes mellitus to achieve glycemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycemic control. Lixisenatide is currently approved in over 60 countries worldwide for the

treatment of adults with type 2 diabetes, with commercial launches in most EU countries, Japan, Brazil, Mexico and other markets. Lixisenatide is an investigational product in the U.S.

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, 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, 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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