Sanofi Announces that First LixiLan Phase III Study Met Primary Endpoint

Paris, France - July 29, 2015 - Sanofi announced today that the LixiLan-O Phase III clinical trial met its primary objective in patients with type 2 diabetes treated with metformin. The fixed-ratio combination of insulin glargine 100 units/mL and lixisenatide, a GLP-1 RA, demonstrated statistically superior reduction in HbA1c (average blood glucose over the previous three months) compared with lixisenatide and compared with insulin glargine 100 units/mL. Overall, the fixed-ratio combination had a safety profile reflecting those of lixisenatide and insulin glargine 100 units/mL.

"*Meeting the primary objective of this important Phase III study highlights the potential clinical value of this investigational therapeutic option,"* said Dr. Elias Zerhouni, President, Global R&D at Sanofi. *"We look forward to advancing the LixiLan program and bringing this combination of insulin glargine and lixisenatide to patients."*

The Phase III LixiLan clinical development program began in Q1 2014 and consists of the LixiLan-O and LixiLan-L trials. LixiLan-O investigated the efficacy and safety of a once-daily single injection of the fixed-ratio combination of insulin glargine 100 units/mL and lixisenatide versus treatment with either lixisenatide or insulin glargine 100 units/mL 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. Full results will be communicated in an appropriate scientific forum.

The ongoing LixiLan-L study investigates the efficacy and safety of a once-daily single injection of the 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 a basal insulin with or without oral anti-diabetic drugs. Only metformin, if taken, was continued throughout the study. The study will be completed in Q3 2015.

Following an analysis of results from both Phase III studies, LixiLan-O and LixiLan-L, Sanofi will determine the next steps in the regulatory process. Currently, regulatory submissions are planned for Q4 2015 in the United States and Q1 2016 in the European Union.

About Lantus® (insulin glargine injection)

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. It should be taken once a day at the same time each day to lower blood glucose.
Do not use Lantus to treat diabetic ketoacidosis.

Important Safety Information for Lantus® (insulin glargine injection)

Do not take Lantus 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.

You must 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.

Tell your doctor about other medicines, especially ones commonly called TZDs (thiazolidinediones), and supplements you are taking because they can change the way insulin works. Before starting Lantus, tell your doctor about all your medical conditions including if you have heart failure or other heart problems, liver or kidney problems, are pregnant or planning to become pregnant, or are breast-feeding or planning to breast-feed. If you have heart failure, it may get worse while you take TZDs with Lantus.

The most common side effect of insulin, including Lantus, is low blood sugar (hypoglycemia), which may be serious. Some people may experience symptoms such as shaking, sweating, fast heartbeat, and blurred vision. Severe hypoglycemia may be serious and life threatening. It may cause harm to your heart or brain. Other possible side effects may include swelling, weight gain, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions, including itching and rash. In rare cases, some allergic reactions may be life threatening.

Lantus SoloSTAR is a disposable prefilled insulin pen. Please talk to your healthcare provider about proper injection technique and follow instructions in the Instruction Leaflet that accompanies the pen.

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 50 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. It will be resubmitted to the Food & Drug Administration (FDA) in the third quarter of 2015.

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 policies 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.

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