Sanofi Receives FDA Approval of Adlyxin™ for Treatment of Adults with Type 2 Diabetes

- Adlyxin™ is approved as Lyxumia® in more than 60 countries -

Paris, France - July 27, 2016 - Sanofi announced today that the U.S. Food and Drug Administration (FDA) approved Adlyxin™ (lixisenatide), a once-daily mealtime GLP-1 receptor agonist injection indicated as an adjunct to diet and exercise for the treatment of adults with type 2 diabetes.

"The approval of Adlyxin reaffirms our continued commitment to addressing the challenges faced by people living with diabetes when trying to reach and maintain their individual blood glucose (HbA1c) targets," said Peter Guenter, Executive Vice President, Head, Global Diabetes & Cardiovascular Business Unit, Sanofi. *"We are pleased with this approval, as it offers us the opportunity to continue helping patients treated with basal insulin who remain uncontrolled."*

The approval of Adlyxin was based on FDA review of results from the GetGoal clinical program and findings from the ELIXA trial, which successfully addressed the FDA's request to demonstrate CV safety. The GetGoal clinical program, which included 13 clinical trials involving more than 5,000 adults with type 2 diabetes worldwide, evaluated the safety and efficacy of lixisenatide in adults with type 2 diabetes. All studies of the GetGoal program successfully met the primary efficacy endpoint of HbA1c reduction. The most common adverse events reported for Adlyxin included nausea, hypoglycemia and vomiting.

Adlyxin will be available in a disposable pre-filled pen in a single dose of 20 micrograms. Patients will also receive a disposable pre-filled pen in a single dose of 10 micrograms that they should initiate once daily for 14 days. On Day 15, patients will increase dosage to 20 micrograms once daily.

Adlyxin is approved under the proprietary name, Lyxumia® in more than 60 countries and marketed in over 40. Commercial launches include most EU countries, Japan, Brazil, Mexico and India. Adlyxin was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com.

About Adlyxin

Adlyxin is a once-daily glucagon-like peptide-1 receptor agonist (GLP-1 RA) for the treatment of adult patients with type 2 diabetes mellitus as an adjunct to diet and exercise. GLP-1 is a 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. Adlyxin increases glucose-dependent insulin release, decreased glucagon secretion, and slows gastric emptying.

Indication and Usage

What is Adlyxin (lixisenatide) injection?

Adlyxin is an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes, when used with diet and exercise.

- Adlyxin is not insulin and should not be used instead of a long-acting insulin.

- Adlyxin is not for people with type 1 diabetes or people with diabetic ketoacidosis.
- Adlyxin has not been studied in people with a history of pancreatitis.
- Adlyxin has not been studied in people who use short-acting insulin.
- It is not known if Adlyxin is safe and effective in children.

Important Safety Information for Adlyxin (lixisenatide) injection

What is the most important information I should know about Adlyxin?

Do not share your Adlyxin pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

Adlyxin can cause serious side effects, including:

- inflammation of the pancreas (pancreatitis), which may be severe and lead to death. Stop using Adlyxin and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel pain from your abdomen to your back.

Do not use Adlyxin if you:

- are allergic to lixisenatide or any of the other ingredients in Adlyxin.

Symptoms of severe allergic reaction with Adlyxin may include swelling of your face, lips, tongue, or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, and very rapid heartbeat.

Before using Adlyxin, tell your healthcare provider if you:

- have or have had pancreatitis, stones in your gallbladder, or a history of alcoholism.
- have or have had kidney problems.
- have severe problems with your stomach, such as delayed emptying of your stomach (gastroparesis) or problems with digesting food.
- are pregnant or breastfeeding or plan to become pregnant or breastfeed. It is not known if Adlyxin will harm your unborn baby.

Tell your healthcare provider about all the medicines you take, including prescription medicines (especially antibiotics and birth control pills) and over-the-counter medicines (especially acetaminophen), vitamins, herbal supplements or other medicines to treat diabetes, including sulfonylureas or insulin.

How should I use Adlyxin?

- Check the label on the pen each time you give your Adlyxin injection to make sure you are using the correct medication.
- **You must activate each Adlyxin pen before you use it for the first time.**
- **Do not re-use or share your needles with other people. You may give other people a serious infection, or get a serious infection from them.**
- Inject your dose of Adlyxin under the skin (subcutaneously) of your abdomen, thigh, or upper arm. **Do not inject into a vein.**
- Change (rotate) your injection sites within the area you chose with each dose. Do not use the same spot for each injection.

What are the possible side effects of Adlyxin?

Adlyxin may cause serious side effects including:

- **severe allergic reactions.** Severe allergic reactions can happen with Adlyxin. Stop taking Adlyxin and get medical help right away if you have any symptoms of a severe allergic reaction.
- **low blood sugar (hypoglycemia).** Your risk for getting low blood sugar is higher if you use Adlyxin with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. The dose of your sulfonylurea or insulin medicine may need to be lowered while you use Adlyxin. Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, hunger, fast heartbeat, dizziness, confusion, irritability, sweating and feeling jittery.
  Talk with your healthcare provider about how to treat low blood sugar.

The most common side effects of Adlyxin include:

- nausea, vomiting, headache, diarrhea and feeling dizzy.

Please click here for full Prescribing Information for Adlyxin:
http://products.sanofi.us/adlyxin/adlyxin.pdf

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.

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.: +1 908 981 5497
philipmcnamara@sanofi.com

U.S. Diabetes Communications
Susan Brooks
Tel.: +1 908 981 6566
susan.brooks@sanofi.com