Sanofi Receives FDA Approval of Soliqua™ 100/33 for the Treatment of Adults with Type 2 Diabetes

Paris, France - November 21, 2016 - Sanofi announced today that the U.S. Food and Drug Administration (FDA) approved once-daily Soliqua™ 100/33 (insulin glargine & lixisenatide injection) 100 Units/mL & 33 mcg/mL for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 Units daily) or lixisenatide*.

Soliqua 100/33 is the combination of Lantus® (insulin glargine 100 Units/mL) and lixisenatide, a GLP-1 receptor agonist, in a once-daily injection, studied in a Phase 3 program of more than 1,900 patients. In an insulin intensification study, Soliqua 100/33 showed better HbA1c (average blood sugar over time) lowering versus Lantus with a majority of the 736 patients (55% vs. 30%) achieving the American Diabetes Association target of less than 7% at 30 weeks. Patients treated with Soliqua 100/33 experienced similar rates of documented (less than or equal to 70 mg/dL) hypoglycemia compared to Lantus-treated patients. The most frequently reported adverse events included hypoglycemia, as well as nausea (10%), nasopharyngitis (7%), diarrhea (7%) and upper respiratory tract infection (5%).[1]

Soliqua 100/33 will be delivered in a single pre-filled pen for once-daily dosing covering 15 to 60 Units of insulin glargine 100 Units/mL and 5 to 20 mcg of lixisenatide using SoloStar technology, the most frequently used disposable insulin injection pen platform in the world.[2] Soliqua 100/33 will be available in U.S. retail pharmacies in January 2017.

"Sanofi continues to be a pioneer in developing diabetes therapies and in bringing forward new treatment options for the approximately 50 percent of patients whose blood sugar levels remain uncontrolled on daily basal insulin. Soliqua 100/33 is an alternate new approach that can help adults living with type 2 diabetes uncontrolled on basal insulin or lixisenatide to reach their treatment goal," said Elias Zerhouni, M.D., President, Global R&D, Sanofi.

The combination was submitted for regulatory review in a total of 10 markets, including the EU, where the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for the marketing authorization of the product on November 11, 2016. It has not yet been approved for use by any health authority outside the U.S.

What is SOLIQUA™ 100/33 (insulin glargine and lixisenatide injection) 100 Units/mL and 33 mcg/mL?

SOLIQUA 100/33 is an injectable prescription medicine that contains 2 diabetes medicines, insulin glargine and lixisenatide, that may improve blood sugar (glucose) control in adults with type 2 diabetes, when used with diet and exercise in people who are not controlled with long-acting (basal) insulin (less than 60 units daily) or lixisenatide.

- It has not been studied in people with a history of pancreatitis.

*Lixisenatide was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com. Lixisenatide is approved as Lyxumia® in more than 60 markets worldwide. The tradename in the U.S. is Adlyxin™

- It is not recommended for people who also take lixisenatide or other medicines called GLP-1 receptor agonists.
- It is not for use in people with type 1 diabetes, diabetic ketoacidosis, or who have a stomach problem that causes slow emptying (gastroparesis).
- It has not been studied together with short-acting insulin.
- **It is not known if SOLIQUA 100/33 is safe and effective in children under 18 years of age.**

Important Safety Information for SOLIQUA™ 100/33 (insulin glargine and lixisenatide injection) 100 Units/mL and 33 mcg/mL

What is the most important information I should know about SOLIQUA 100/33?
Do not share your SOLIQUA 100/33 pen with other people, even if the needle has been changed.
SOLIQUA 100/33 can cause serious side effects, including inflammation of the pancreas, which may be life-threatening.

Before using SOLIQUA 100/33, tell your doctor if you have had:
- pancreatitis
- stones in your gallbladder (cholelithiasis)
- a history of alcoholism

These medical problems may make you more likely to get pancreatitis. Stop taking SOLIQUA 100/33 and call your healthcare provider right away if you have pain in your stomach area (abdomen) that is severe, and will not go away. The pain may be felt in the back area. The pain may happen with or without vomiting.

Who should not use SOLIQUA 100/33?
Do not use SOLIQUA 100/33 if you are having an episode of low blood sugar (hypoglycemia) or if you are allergic to insulin glargine, lixisenatide, or any of the other ingredients in SOLIQUA 100/33.

Tell your healthcare provider about all your medical conditions, including if you:
- have or have had symptoms of acute pancreatitis, stones in your gallbladder, or a history of alcoholism.
- have or have had liver or kidney problems.
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZD (thiazolidinediones).
- have severe problems with your stomach, such as slowed emptying of your stomach or problems digesting food.
- are pregnant or plan to become pregnant. It is not known if SOLIQUA 100/33 will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SOLIQUA 100/33 passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including all prescription and over-the-counter medicines, vitamins, and herbal supplements. SOLIQUA 100/33 may affect the way some medicines work

How should I use SOLIQUA 100/33?
- **Do not take more than 60 units of SOLIQUA 100/33 each day**. If you take too much, it can cause severe nausea and vomiting. Do not take SOLIQUA 100/33 with other GLP-1

receptor agonists. If you take too much SOLIQUA 100/33, call your healthcare provider or go to the nearest hospital emergency room right away.

- Only use SOLIQUA 100/33 that is clear, colorless to almost colorless. If you see small particles, return it to your pharmacy for replacement.
- **Do not** mix SOLIQUA 100/33 in any other type of insulin or liquid medicine prior to injection.
- **Do not** remove SOLIQUA 100/33 from the pen with a syringe.
- **Do not re-use or share needles with other people. You may give other people a serious infection, or get a serious infection from them.**
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar should be and when you should check.

SOLIQUA 100/33 may cause serious side effects, including:

- **Serious allergic reactions.** Severe allergic reactions can happen with SOLIQUA 100/33. Stop taking it and get help right away if you have any symptoms of a severe allergic reaction. Symptoms may include swelling of your face, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, and very rapid heartbeat.
- **Low blood sugar (hypoglycemia). Your risk for getting low blood sugar is higher if you take another medicine that can cause low blood sugar.** Signs and symptoms of low blood sugar may include:
  - headache
  - weakness
  - fast heartbeat
  - dizziness
  - irritability
  - feeling jittery
  - drowsiness
  - hunger
  - confusion
  - sweating
- **Kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may worsen kidney problems.
- **Low potassium in your blood (hypokalemia).**
- **Heart failure.** Taking certain diabetes pills called TZDs (thiazolidinediones) with SOLIQUA 100/33 may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure, it may get worse while you take TZDs with SOLIQUA 100/33. Tell your healthcare provider if you have any new or worse symptoms of heart failure, including shortness of breath, swelling of your ankles or feet, sudden weight gain.

The most common side effects of SOLIQUA 100/33 may include:

- low blood sugar (hypoglycemia)
- nausea
- headache
- stuffy or runny nose and sore throat
- allergic reactions
- diarrhea
- upper respiratory tract infection

Nausea and diarrhea usually happen more often when you start using SOLIQUA 100/33.

Please click here for full Prescribing Information for SOLIQUA 100/33 (insulin glargine & lixisenatide injection) 100 Units/mL & 33 mcg/mL: http://products.sanofi.us/Soliqua100-33/Soliqua100-33.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 regarding the marketing and other potential of Soliqua, or regarding potential future revenues from Soliqua. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of Soliqua, the absence of guarantee that Soliqua will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to Soliqua, 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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2. Data on file: IMS Q_Global Q4/2015, V.Kircher.