

# Sanofi Announces Soliqua<sup>™</sup> 100/33 Now Available in the U.S.

**Paris, France – January 4, 2017 –** <u>Sanofi</u> announced today that Soliqua<sup>™</sup> 100/33 (insulin glargine 100 Units/mL & lixisenatide<sup>\*</sup> 33 mcg/mL injection) is now available by prescription in U.S. pharmacies. Soliqua 100/33 is indicated for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 Units daily) or lixisenatide.

"We are encouraged by the potential of Soliqua 100/33, which has demonstrated superior HbA1c lowering versus Lantus," said Peter Guenter, Executive Vice President, Head, Global Diabetes & Cardiovascular Business Unit, Sanofi. "By offering Soliqua 100/33 – a product containing both a basal insulin and a GLP-1 therapy – at a competitive price while facilitating patient access, we believe we are providing value to patients and the healthcare system."

In the labeled clinical trial, once-daily Soliqua 100/33 demonstrated statistical superiority for the change in HbA1c from baseline to week 30 (p<0.0001) versus Lantus<sup>®</sup>, the most prescribed basal insulin in the world.<sup>1,2,3</sup> The most common side effects reported in the clinical program included low blood sugar, nausea, stuffy or runny nose and sore throat, diarrhea, upper respiratory tract infection and headache. Soliqua 100/33 is delivered in a single pre-filled SoloStar pen with a dose range covering from 15 to 60 Units and two starting doses to support patients' insulin needs. Soliqua 100/33 was approved by the U.S. Food and Drug Administration (FDA) on November 21, 2016.

The daily Wholesale Acquisition Cost (WAC) price of Soliqua 100/33 is \$127 for a 300 Unit pen, which equals \$19.90 per day at the average final dose of 47 Units used in the labeled clinical trial.

Sanofi is offering Soliqua 100/33 at a \$0 co-pay<sup>\*\*</sup> for eligible U.S. patients with commercial insurance and is working to secure coverage for Soliqua 100/33 on health plans nationwide. Sanofi is also offering a tailored support program, Soliqua 100/33 COACH, at no cost to adults living with type 2 diabetes who have been prescribed Soliqua 100/33 by their doctor.

"Healthcare professionals need a broad range of treatments to individualize a patient's diabetes care, particularly for the many adults living with diabetes who continue to face challenges in controlling their blood sugar levels even after treatment with basal insulin," said George Grunberger, M.D., FACP, FACE, Chairman, Grunberger Diabetes Institute. "This combination product provides a new option for many patients uncontrolled on basal insulin therapy or lixisenatide."

## 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 Consumer Healthcare. Sanofi is listed in Paris (EURONEXT: <u>SAN</u>) and in New York (NYSE: <u>SNY</u>).

#### 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 the product, or regarding potential future revenues from the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans", "looks forward" 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 the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, 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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\* Lixisenatide was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com.

<sup>\*\*</sup> With the SOLIQUA 100/33 Savings Card, patients may be eligible for the \$0 CO-PAY offer for the next 12 months. Restrictions apply. This offer is for commercially insured patients and is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, or TRICARE, or similar federal or state programs including any state pharmaceutical programs. Void where prohibited by law. Savings card carries maximum savings of \$700 off per pack for the duration of the program. Savings may vary depending on patient's out-of-pocket costs. Upon registration, patient receives all program details. Sanofi US reserves the right to rescind, revoke, or amend the program without notice.

### References

- 1. Data on file: IMS Q\_Global Q4/2015, V.Kircher.
- 2. Rosenstock J, et al. Presentation 186-O presented at American Diabetes Association (ADA) 76th Scientific Sessions, New Orleans, LA, U.S., 2016. Available from Date accessed: November 2016.
- 3. Aroda V, et al. Presentation 238-O presented at American Diabetes Association (ADA) 76th Scientific Sessions, New Orleans, LA, U.S., 2016. Available from Date accessed: November 2016.