SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Soliqua® Phase 3 results significantly lowered blood sugar levels compared to GLP-1 receptor agonist treatments

* Patients switched to Soliqua reached an average blood sugar below the American Diabetes Association recommended level of 7%
* Full Phase 3 data presented today at the American Diabetes Association (ADA) 79th Scientific Sessions

PARIS – June 9, 2019 – In a Phase 3 study[1] evaluating adults with type 2 diabetes inadequately controlled by GLP-1 receptor agonist (GLP-1 RA) treatments, Soliqua®/Suliqua®[2] (insulin glargine 100 Units/mL and lixisenatide) met the primary study objective by demonstrating a statistically superior reduction of average blood sugar level (HbA_{1c}) after 26 weeks, compared with continuing GLP-1 RA treatment.

The LixiLan-G study included either a daily or once-weekly GLP-1 RA treatment as comparator. More patients who switched to Soliqua achieved HbA_{1c} levels below 7%, a target recommended by the ADA, compared with those who stayed on previous GLP-1 RA therapy. More patients who switched to Soliqua also achieved the composite endpoint of HbA_{1c} below 7% without documented symptomatic hypoglycemia (low blood sugar levels).

The study showed a safety profile consistent with the established profiles of the treatments studied: the most common classes of adverse event were gastrointestinal events (i.e., nausea, diarrhea and or vomiting) and hypoglycemia.

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[1] Blonde L et al, Presentation #149 OR, American Diabetes Association 79th Scientific Sessions, June 9, San Francisco, CA, U.S.

[2] Soliqua® is an injectable prescription medicine that contains two diabetes medicines, insulin glargine and lixisenatide. Soliqua® is marketed in the EU as Suliqua®, where it is indicated in combination with metformin for the treatment of adults with type 2 diabetes mellitus to improve glycemic control when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product or with basal insulin. It is marketed in the U.S. as Soliqua® 100/33, where it is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It is marketed as Soliqua® in other geographies where it is approved

The full Phase 3 data results were presented today for the first time as an oral presentation at the 79th Scientific Sessions of the ADA in San Francisco.

> *"We are committed to providing people living with diabetes a broad range of options that can help support personalized care,"* said Rachele Berria, Global Head of Diabetes Medical Affairs at Sanofi. *"As the first comparison between Soliqua and both daily and weekly GLP-1 RA treatments, this study provides physicians with new data that they could use when considering Soliqua as a part of a personalized treatment plan."*

About the study

The LixiLan-G study included 514 adults with type 2 diabetes who were inadequately controlled on a GLP-1 RA (either once-daily liraglutide or twice-daily exenatide, or once-weekly exenatide extended release, albiglutide or dulaglutide) and metformin (with or without pioglitazone, with or without a sodium-glucose transport protein 2 inhibitor [SGLT2i]). Participants were randomized to either switch to Soliqua or continue their previous GLP-1 RA treatment, while maintaining their other pre-trial anti-diabetic medication. Adherence to allocated treatment was monitored and reinforced throughout the study.

The primary objective was to demonstrate superior reduction of HbA_{1c} with Soliqua versus continuation of the previous GLP-1 RA after 26 weeks. Secondary objectives included comparison of the overall efficacy and safety of Soliqua to continued GLP-1 RA treatment.

After 26 weeks, patients who switched to Soliqua saw a 0.6% greater reduction in HbA_{1c} versus continuing treatment with a GLP-1 RA:

	Soliqua	**GLP-1 RA**
Mean HbA_{1c} at baseline	7.86%	7.88%
Mean HbA_{1c} at Week 26	6.7%	7.4%
Reduction in HbA_{1c}	-1.02%	-0.38%
Least squares mean difference	-0.64%	
95% Confidence interval	-0.77 to -0.51	
p-value	<0.0001	

More patients who switched to Soliqua achieved HbA_{1c} below the 7% target recommended by the ADA versus those treated with GLP-1 RA (difference: 36%, $p < 0.0001$). The study also evaluated composite targets

of HbA_{1c} below 7% without documented symptomatic hypoglycemia (<54 mg/dL or ≤70 mg/dL, respectively):

	Soliqua	GLP-1 RA
% of patients achieving HbA_{1c} < 7%	62%	26%
% of patients achieving HbA_{1c} < 7% with no documented (≤70 mg/dL) symptomatic hypoglycemia	43%	25%
% of patients achieving HbA_{1c} < 7% with no documented (<54 mg/dL) symptomatic hypoglycemia	57%	25%

The study showed a safety profile consistent with previous studies: 22% of patients who switched to Soliqua experienced gastrointestinal events (nausea, diarrhea or vomiting), compared with 10% of patients who continued previous treatment with GLP-1 RA. Rates of hypoglycemia were also consistent with the established safety profiles of the treatments: 9% of patients who treated with Soliqua experienced at least one event, compared with <1% who remained on previous GLP-1 RA therapy.

Participants treated with Soliqua were followed for a further 26 weeks. Data from this extension period will be presented at a later date.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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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" 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, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.