

## **New Soliqua®\* data shows improved blood sugar control without weight gain versus premixed insulin**

- Study also shows more people on Soliqua had improved blood sugar control without weight gain and without increased blood sugar events (hypoglycemia) in first head-to-head comparison with premixed insulin

### **LAVAL— 28 JUNE 2021**

A new study of Soliqua (insulin glargine 100 Units/mL and lixisenatide, iGlarLixi) met its two primary endpoints and all key secondary endpoints in a head-to-head comparison against premixed insulin (biphasic insulin aspart 30, BIAsp 30) in adults living with type 2 diabetes, the most common form of diabetes, uncontrolled on insulin and one or two oral anti-diabetic medicines. The findings were presented today at the American Diabetes Association (ADA) 81<sup>st</sup> Scientific Sessions<sup>1</sup> and simultaneously published in *Diabetes Care*.<sup>2</sup>

The study met both primary endpoints with Soliqua demonstrating noninferiority of blood sugar (HbA<sub>1c</sub>) reduction and superiority on body weight change from baseline compared to premixed insulin. The study also met its key secondary endpoints with Soliqua achieving a greater proportion of people reaching a HbA<sub>1c</sub> target of <7% without weight gain, a greater proportion of people reaching a HbA<sub>1c</sub> target of <7% without weight gain and without hypoglycemia, and superiority in reduction of HbA<sub>1c</sub> compared with those using premixed insulin.

*“Concerns about hypoglycemia and weight gain are known barriers when advancing basal insulin therapy, especially with complex insulin regimens,”* says Julio Rosenstock, Director of the Dallas Diabetes Research Center at Medical City, Dallas, TX, and main author of the study. *“These results show improved outcomes with iGlarLixi over BIAsp 30, demonstrating better glucose control without body weight gain and less hypoglycemia. This combined benefit could help clinicians consider advancing basal insulin therapy by switching to a once-daily fixed-ratio combination of basal insulin plus a GLP-1 receptor agonist rather than switching to a twice-daily premixed insulin regimen.”*

A secondary analysis also found that study participants using Soliqua reported greater improvements in patient-reported outcomes compared to premixed insulin as measured by Treatment-Related Impact Measure Diabetes (TRIM-D) and patient- and physician-rated Global Treatment Effectiveness Evaluation (GTEE) scores.<sup>3</sup> These tools include measurements of treatment burden, daily life, diabetes management, compliance, psychological health, and treatment effectiveness.

*“While premixed is used by around 40% of people taking insulin globally to manage their type 2 diabetes today, recent real-world evidence suggests only 18.2% of people using it reach their blood sugar goal,”<sup>4,5</sup>* said Sandra Silvestri, M.D., Ph.D., Global Medical Head of General Medicines at Sanofi. *“Today’s results provide further information on Soliqua’s impact and patient-reported outcomes that could be considered by healthcare providers.”*

Safety findings were in line with the established profiles of Soliqua and premixed insulin.

### **About the SoliMix study**

The SoliMix study was a 26-week, randomized controlled trial of 887 adults living with type 2 diabetes who were uncontrolled on insulin plus metformin with or without a sodium-glucose cotransporter-2 inhibitor (SGLT-2i). The study compared the efficacy and safety of Soliqua compared to a commonly used premixed insulin (BIAsp 30). Participants were randomized to switch from their prior insulin to either Soliqua once daily or premixed insulin twice daily, with starting doses determined and adjusted weekly. Any metformin or SGLT-2i treatment was maintained through the study period.

The study met its two primary endpoints and all three of its key secondary endpoints.

Safety findings were in line with the established profiles of both treatments. The most commonly reported adverse events in the study were hypoglycemia (31.2% Soliqua, 42.4% premixed insulin), nausea (7.7% Soliqua, 0% premixed insulin), headache (2.5% Soliqua, 0.5% premixed insulin), dizziness (1.4% Soliqua, 0.5% premixed insulin), and vomiting (1.1% Soliqua, 0.2% premixed insulin).

\*

*SOLIQUA®, a fixed ratio combination of insulin glargine and lixisenatide, once daily injection, is indicated in combination with metformin as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus inadequately controlled on: [PM p. 4A] basal insulin (<60 units daily) alone or in combination with metformin, a glucagon-like peptide-1 receptor agonist (GLP-1 RA) in combination with metformin*

### **References**

- Rosenstock, J., et al. “Advancing Therapy in Uncontrolled Basal Insulin-Treated Type 2 Diabetes (T2D): Better Clinical Outcomes with iGlarLixi vs Premix 70/30 in the SoliMix Trial”, Presentation 234-OR, American Diabetes Association (ADA) 81<sup>st</sup> Scientific Sessions (virtual event), June 28, 2021.
- Rosenstock, J., et al. Advancing therapy in suboptimally controlled basal insulin-treated type 2 diabetes: Clinical outcomes with iGlarLixi versus premix BIAsp 30 in the SoliMix randomized controlled trial. *Diabetes Care*. 2021 Jun 28.
- Polonsky, W., et al. “Improved Treatment Perceptions with iGlarLixi vs Premix Insulin in Type 2 Diabetes (T2D) Uncontrolled on Basal Insulin (BI) + Oral Antihyperglycemic Drugs (OADs): Patient-reported Outcomes (PROs) of the SoliMix Trial”, Presentation 747-P, American Diabetes Association (ADA) 81<sup>st</sup> Scientific Sessions (virtual event), June 28, 2021.
- Source: Market sales data, IQVIA
- Jude E., et al. Effectiveness of premix insulin in type 2 diabetes: a retrospective UK cohort study *Diabetes Obes Metab*. 2021;23:929-937.

## 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.

## Media Relations Contact

Emilija Businskas

[emilija.businskas@sanofi.com](mailto:emilija.businskas@sanofi.com)

## Investor Relations - Paris

Eva Schaefer-Jansen

Arnaud Delepine

Nathalie Pham

## Investor Relations – North America

Felix Lauscher

Fara Berkowitz

Suzanne Greco

## IR main line:

Tel.: +33 (0)1 53 77 45 45

[investor.relations@sanofi.com](mailto:investor.relations@sanofi.com)

<https://www.sanofi.com/en/investors/contact>

### **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 fact that product may not 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 and market conditions, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties 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, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

For further information: Media Relations Contact: Emilija Businskas, [emilija.businskas@sanofi.com](mailto:emilija.businskas@sanofi.com); Investor Relations - Paris: Eva Schaefer-Jansen; Arnaud Delepine; Nathalie Pham; Investor Relations - North America: Felix Lauscher; Fara Berkowitz; Suzanne Greco; IR main line: Tel.: +33 (0)1 53 77 45 45, [investor.relations@sanofi.com](mailto:investor.relations@sanofi.com), <https://www.sanofi.com/en/investors/contact>

---