SANOFI AT ADA
77TH SCIENTIFIC SESSIONS
June 09–13, San Diego

MEDIA INFORMATION

For medical journalists outside the U.S. only

New Analysis Shows Sanofi's Soliqua® 100/33 Lowered HbA_{1c} by More Than 2 Percent in Patients with Screening Levels Greater than 9 Percent

- All subgroups treated with Soliqua 100/33 achieved a mean HbA_{1c} of below 7 percent after 30 weeks -

San Diego, CA, U.S. – June 10, 2017 – Soliqua® 100/33 (insulin glargine & lixisenatide injection) 100 Units/mL & 33 mcg/mL lowered mean blood sugar levels (HbA_{1c}) by between 1.09 and 2.41 percent after 30 weeks in adults with type 2 diabetes previously treated with between 15 and 40 units of basal insulin daily. This new post-hoc analysis of data from the LixiLan-L Phase 3 study, which grouped participants by HbA_{1c} level at screening, also showed that all subgroups reached a mean HbA_{1c} below 7 percent during the study period.

"*Lowering elevated HbA_{1c} is an important treatment goal in people with diabetes,*" said Riccardo Perfetti, Vice President, Head of Global Medical Affairs Diabetes, Sanofi. "*This analysis demonstrated the substantial blood sugar lowering effect that can be achieved with Soliqua 100/33, and also its potential to help adults reach HbA_{1c} levels below 7 percent, which is recommended as a treatment goal by bodies such as the American Diabetes Association for many adults with diabetes.*"[1]

Soliqua® 100/33, which is used in conjunction with diet and exercise, is marketed as Suliqua® in the EU.

The abstract is titled "**iGlarLixi Reduces A1C to a Greater Extent Than Basal Insulin Therapy Regardless of A1C Levels at Screening**" (Niemoeller E et al. Poster presentation 1079-P, American Diabetes Association (ADA) 77th Scientific Sessions, San Diego, CA, U.S., June 10).

Summary of analysis

This post-hoc analysis reviewed data from the LixiLan-L pivotal Phase 3 trial, which compared the effectiveness of Soliqua 100/33 and insulin glargine 100 Units/mL in 736 adults whose type 2 diabetes was not adequately controlled at screening on between 15 and 40 units of basal insulin daily, alone or combined with one or two oral anti-diabetic agents. The primary outcome of the LixiLan-L study, a statistically significant reduction in HbA_{1c} compared with insulin glargine 100 Units/mL, was previously reported.[2]

The analysis evaluated data for the 660 participants who completed the 30 week study period. Patients were split in three categories based on HbA_{1c} at screening: HbA_{1c} ≤8%, HbA_{1c} >8% to ≤9%, and HbA_{1c} >9%. Change from screening to study end was determined

with ANOVA analysis of 30-week completers in the modified intention-to-treat (mITT) population. LS mean reductions in HbA_{1c} for the Soliqua 100/33 treatment groups after 30 weeks were 1.09%, 1.44% and 2.41%, respectively. The mean HbA_{1c} observed for each subgroup was ≤7% with Soliqua 100/33 (6.65%, 6.99% and 6.97% respectively), but >7% with insulin glargine 100 Units/mL alone (7.22%, 7.42% and 7.66%, respectively). Reductions in HbA_{1c} were greater for Soliqua 100/33 in all defined categories versus insulin glargine 100 Units/mL ($p<0.0001$ for all comparisons).

As previously reported for LixiLan-L,[2] incidence of documented (≤70 mg/dL / 3.9 mmol/L) symptomatic hypoglycemia was similar with Soliqua 100/33 (40% of patients; 3.0 events/year; E/Y) and insulin glargine 100 Units/mL (42.5% of patients; 4.2 E/Y). With Soliqua 100/33, 10.4% of participants experienced nausea, and 3.6% experienced vomiting; while with insulin glargine 100 Units/mL 0.5% of participants experienced nausea and 0.5% experienced vomiting.

Related multimedia resources available here.

About Soliqua®

Soliqua is the fixed-ratio combination of insulin glargine 100 Units/mL and the GLP-1 agonist lixisenatide, administered as a single once-daily injection using a pre-filled pen. Soliqua is marketed as Soliqua® 100/33 in the U.S, and as Suliqua® in the EU. In the U.S., it is indicated for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 Units daily) or lixisenatide. In the EU, it is indicated for use in combination with metformin 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.

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: SAN) and in New York (NYSE: SNY).

References

1. American Diabetes Association, Diabetes Care Jan 2017, 40 (Supplement 1) S48-S56; DOI: 10.2337/dc17-S009.
2. Aroda VR, et al. Diabetes Care. 2016, DOI: 10.2337/dc16-1495.

Contacts:

Corporate Communications
Mai Tran
Tel.: +33 (0) 1.53.77.46.46
mai.tran@sanofi.com

SANOFI