SANOFI

Press Release

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

# Positive results in Phase 3 trial for Toujeo® in children and adolescents with type 1 diabetes

* CHMP adopts positive opinion for expanded indication for Toujeo in children and adolescents (aged 6 to 17 years) with diabetes

**PARIS – November 4, 2019** – Children and adolescents (aged 6 to 17 years) living with type 1 diabetes achieved comparable reduction in average blood sugar ($HbA_{1c}$) and similar risk of low blood sugar events with Toujeo® (insulin glargine 300 Units/mL) compared to insulin glargine 100 Units/mL (Gla-100), according to results presented at the International Society for Pediatric and Adolescent Diabetes 45th Annual Conference in Boston, Massachusetts.[1]

> *"We know that living with type 1 diabetes means dealing with highs and lows in blood sugar, which are worrying and present substantial challenges for young people,"* said Prof. Dr. Thomas Danne, Director of the Department of General Pediatrics and Endocrinology/Diabetology at the Children's Hospital on the Bult, Hannover Medical School, Germany. *"In addition to the trial demonstrating safety and efficacy, the percentage of patients with severe hypoglycemia, and the percentage with hyperglycemia with ketosis, were numerically lower with Toujeo."*

The trial, EDITION JUNIOR, is the first randomized, controlled trial comparing Toujeo vs Gla-100 in this group of patients. The study met its primary endpoint with comparable reductions in average blood sugar over 6 months with both treatments and similar risk of low blood sugar events (hypoglycemia). The percentages of patients who experienced severe hypoglycemia and who experienced high blood sugar (hyperglycemia) with ketosis were numerically lower with Toujeo. As these are serious short-term complications, these findings are clinically important for people with type 1 diabetes.

Based on these data, the European Medicines Agency's Committee for Medicinal Products for Human Use adopted a positive opinion on October 17, recommending expanding the current indication for Toujeo in the Europe Union for the treatment of diabetes mellitus in adolescents and children (6 years and older).

> *"Across the globe, between 50 and 80 percent of young people living with type 1 diabetes need more treatment options to help them achieve an average blood sugar level below 7.5%,"* said Dietmar Berger, Global Head of Development at Sanofi. *"By taking this step toward investigating an additional option for children and adolescents living with diabetes, we hope to provide another treatment for them and their physicians, to develop an individualized treatment plan that helps patients better manage their disease."*

The European Commission will make a final decision on this additional indication in the coming months.

## About the study

The EDITION JUNIOR study[1] compared Toujeo to Gla-100 in 463 children and adolescents (aged 6 to 17 years) treated for type 1 diabetes for at least one year and with $HbA_{1c}$ between 7.5% and 11.0% at screening. Participants continued to use their existing mealtime insulin.

The study met its primary endpoint, confirming non-inferior reduction of $HbA_{1c}$ with Toujeo vs Gla-100 after 26 weeks (mean reduction 0.4% vs 0.4%; difference: 0.004%, 95% CI -0.17 to 0.18; upper bound was below the pre-specified non-inferiority margin of 0.3%).

Over the same period, a comparable number of patients experienced one or more anytime (24h) documented low blood sugar (hypoglycemia) events. Numerically fewer patients using Toujeo experienced severe hypoglycemia, or experienced one or more episodes of high blood sugar (hyperglycemia) with ketosis compared, with those using Gla-100.

The number of adverse events was comparable between the two treatment groups (65.2% vs 65.8% of patients reported any treatment-emergent adverse event). No unexpected safety concerns were reported, based on the established profiles of both products.

| | **Toujeo (n=233)** | **Gla-100 (n=228)** |
|---|---|---|
| One or more event of severe and/or documented (≤ 70 mg/dL) hypoglycemia (24 h) | 226 (97%) | 223 (97.8%) |
| | *RR: 0.99*<br>*95% CI: 0.96 to 1.02* | |
| One or more event of severe and/or documented (< 54 mg/dL) hypoglycemia (24 h) | 187 (80.3%) | 191 (83.8%) |
| | *RR: 0.96*<br>*95% CI: 0.88 to 1.04* | |
| One or more episode of severe hypoglycemia (24 h) | 14 (6.0%) | 20 (8.8%) |
| | *RR: 0.68*<br>*95% CI (0.35 to 1.30)* | |
| One or more event of hyperglycemia with ketosis (ketones ≥1.5 mmol/L) | 19 (8.2%) | 26 (11.4%) |

The study design includes a further 6-month safety follow-up period, which will be reported separately.

**References**


1. Danne T et al., “Insulin Glargine 300 U/mL (Gla-300) provides effective glycemic control in youths with type 1 diabetes (T1D): the EDITION JUNIOR study”, Poster presentation P240, ISPAD 45th

Annual Conference, Boston MA, U.S., October 31, 2019. Available via http://www.professionalabstracts.com/ispad2019/Iplanner/#/presentation/216 [Accessed October 2019].

**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.

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