

Sanofi presents results from the first head-to-head study comparing Toujeo® to insulin degludec

- **Toujeo® (insulin glargine injection 300 Units/mL) met primary endpoint in lowering blood sugar levels and was non-inferior to insulin degludec in adults with type 2 diabetes not previously on insulin.**
- **Incidence and rate of low blood sugar (hypoglycemia) events were reduced with Toujeo® in the first 12 weeks compared to insulin degludec, and comparable from weeks 13-24 and the full 24-week study period.**

Laval, Québec - June 27, 2018 – Sanofi (NYSE: SNY; Euronext: SAN) presented positive non-inferiority results of the BRIGHT study comparing its long-acting insulin Toujeo® to insulin degludec at the American Diabetes Association (ADA) 78th Scientific Sessions in Orlando, Florida.¹

At the end of the BRIGHT study, Toujeo® demonstrated comparable blood sugar (HbA1c) control versus insulin degludec (-1.64% vs. -1.59%, respectively). During the first 12 weeks of therapy, a period when patients and physicians work to determine the most appropriate individual insulin dose, Toujeo® reduced the rate of hypoglycemia events by 23 percent and the incidence of hypoglycemia events by 26 percent, compared to insulin degludec ($p < 0.05$).² During the subsequent 12 weeks of the study (treatment period: 13-24 weeks), the two treatments showed comparable rate and incidence of hypoglycemia events.

"Hypoglycemia is a concern for people with diabetes, particularly in the initial period of dose adjustment," says Alice Cheng, Associate Professor of Endocrinology, University of Toronto, Toronto, Canada, and a primary investigator of the study. "Experiencing hypoglycemia, particularly in this early treatment period, could lead to patients discontinuing their treatment."

The incidence of hypoglycemia at any time of the day during the 24-week treatment period was also comparable between Toujeo® and insulin degludec (66.5% and 69.0%, respectively).

Results of the BRIGHT study:

The randomized controlled trial compared the efficacy and safety of Toujeo® versus insulin degludec at 24 weeks. The study randomized 929 adults with type 2 diabetes to once-daily insulin glargine injection 300 Units/mL (Toujeo®) or insulin degludec 100 Units/mL (Tresiba®). Before randomization, participants were inadequately controlled with tablets (oral anti-hyperglycemic drugs, OADs), with or without a glucagon-like peptide-1 (GLP-1) receptor agonist, and had not previously started insulin therapy.¹

"Canadians with T2D may need to take insulin to achieve their target glucose levels while minimizing the risk of hypoglycemia and help to reduce the risks of complications. These complications could lead to heart or kidney disease, loss of vision and other irreversible physical consequences," says Dr. Rémi Rabasa-Lhoret, associate professor in the Department of Nutrition at the Université de Montréal and Director of the metabolic diseases laboratory at the Montreal Clinical Research Institute. "The use of basal insulins such as insulin glargine 300 Units/mL (Toujeo®) makes it possible to lower the amount of glucose in the blood. This second generation of basal insulin has shown an improved hypoglycemia profile over first generation basal insulins."

The study met its primary endpoint demonstrating a reduction in blood sugar (HbA1c) levels comparable with Toujeo® and insulin degludec from baseline to week 24 (at a non-inferiority margin of 0.3% and difference between treatments of -0.05% [95% CI -0.15 to 0.05%]).¹

Over the 24-week period, incidence and event rates of confirmed (≤ 3.9 mmol/L and ≤ 3.0 mmol/L) hypoglycemia at any time of day were comparable between Toujeo® and insulin degludec. During the titration period (0-12 weeks), confirmed hypoglycemia event rates were lower by 23 percent (≤ 3.9 mmol/L) and 43 percent (≤ 3.0 mmol/L) with Toujeo®. In this period, the incidence of confirmed hypoglycemia was also reduced by 26 percent (≤ 3.9 mmol/L) and 37 percent (≤ 3.0 mmol/L) with Toujeo®. Hypoglycemia incidence and event rates were comparable in the maintenance time period (13-24 weeks).²

Diabetes in Canada

Diabetes affects approximately 3.4 million Canadians, of which type 2 diabetes accounts for 90% of cases^{3,4}. It is estimated that 5.7 million Canadians have prediabetes; this condition is characterized by blood glucose levels above normal, but not high enough to be diagnosed as diabetes. Fifty percent of individuals with prediabetes will develop type 2 diabetes⁵. Left untreated, diabetes can lead to many serious complications, such as heart disease, kidney disease, loss of vision and amputation of the lower limbs.

“This study demonstrates Sanofi Canada’s commitment with regard to the effort and energy invested by healthcare professionals to help patients receive the best possible care they need in terms of available treatments stemming from the most recent developments in research on diabetes management,” concluded Dr. Hisham A.S. Mahmoud, Medical Director at Sanofi Canada.

References

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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 entities in Canada employ approximately 1,900 people. In 2017 we invested over \$131 million in R&D in Canada, creating jobs, business and opportunity throughout the country.


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