

Sanofi declares positive results from phase 3 trial for Toujeo

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



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.

“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.