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Toujeo receives positive opinion from CHMP

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Toujeo has demonstrated a more stable and a prolonged glycemic control that lasts beyond 24 hours compared with Lantus (insulin glargine [rDNA origin] injection, 100 U/mL) with low within-individual, within-day blood sugar variability.

"Today's CHMP opinion is another step forward to make Toujeo available to people living with diabetes who are currently not at their glycemic target, or are about to start insulin therapy," said Mr Pierre Chancel, senior VP, global diabetes, Sanofi. "We are confident that we can soon add this new treatment option to our portfolio to help patients reach their blood sugar goals."

The CHMP positive opinion of Toujeo is based on results from the EDITION clinical trial program, a worldwide and extensive series of phase III studies evaluating the efficacy and safety of Toujeo compared to Lantus in more than 3,500 adults with type 1 or type 2 diabetes who were uncontrolled on their current therapy.

Toujeo demonstrated effective blood sugar control, with a favorable safety profile.

Toujeo significantly lowered hypoglycemic (low blood sugar) risk in people with type 2 diabetes at any time of the day and night-time as compared with Lantus.

The European Commission (EC) is expected to make a final decision on granting marketing authorization for Toujeo in the EU in the coming months.

Toujeo was approved by the US Food and Drug Administration and is under review by other regulatory authorities around the world.

Once approved, Toujeo will be available in the Toujeo SoloSTAR, a disposable prefilled pen which contains 450 insulin units (IU), and it has a maximum single injection dose of 80 IU.