BioSpectrum the business of Bio & Health Sciences

Sanofi's diabetes drug approved in EU

29 April 2015 | News | By BioSpectrum Bureau

Sanofi's diabetes drug approved in EU

Sanofi announced that the European Commission has granted marketing authorization in Europe for Toujeo (insulin glargine [rDNA origin] injection, 300 U/mL), a next-gen basal insulin for the treatment of type 1 and type 2 diabetes mellitus in adults.

"The EU marketing authorization for Toujeo represents a significant milestone for Sanofi, expanding our integrated portfolio of solutions for people with diabetes in Europe," commented Mr Pierre Chancel, SVP, global diabetes, Sanofi. "Toujeo gives people with diabetes and their physicians a new option to manage their condition, and also reinforces our commitment to

continue improving the quality of diabetes care."

The European Commission's decision to grant marketing authorization in Europe for Toujeo is based on results from the EDITION clinical trial program, a series of worldwide phase III studies evaluating the efficacy and safety of Toujeo compared with Lantus (insulin glargine [rDNA origin] injection, 100 U/mL) in more than 3,500 adults with type 1 or type 2 diabetes who were uncontrolled on their current therapy.

Blood sugar control with Toujeo was comparable to Lantus, with a favorable safety profile.

The incidence of confirmed hypoglycemia was lower with Toujeo as compared to Lantus, both at any time of the day and at night, in people with type 2 diabetes.

Toujeo also demonstrated more stable and more predictable glycemic control and low within-individual blood sugar variability that lasted beyond 24 hours compared with Lantus in people with type 1 diabetes.

"Many people living with diabetes and requiring insulin are still not achieving adequate blood sugar control," said Prof Robert Ritzel, head of the Clinic of Endocrinology, Diabetology and Addiction Medicine, Klinikum Schwabing, StÃ¤dtisches Klinikum MÃ¼nchen GmbH, Munich, Germany. "By providing glycemic stability and less variability, as well as reducing hypoglycemic events in people with type 2 diabetes, Toujeo provides a new way to address these unmet needs."

Marketing authorization in Europe for Toujeo is applicable to the 28 member states of the European Union, as well as Iceland, Lichtenstein and Norway, and follows the February 26, 2015 positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).

Toujeo has been approved by the US Food and Drug Administration (FDA) and is under review by other regulatory authorities around the world.