

Japan Okays Sanofi's Basal Insulin Drug

06 July 2015 | News | By BioSpectrum Bureau

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French pharma giant Sanofi has announced that the Ministry of Health, Labor and Welfare (MHLW) in Japan has granted marketing authorization for insulin glargine [rDNA origin] injection, 300 U/mL, a next-generation basal insulin for the treatment of type 1 and type 2 diabetes mellitus, where treatment with insulin is needed. Known as Toujeo in the US and Europe, the new insulin treatment will be available in Japan under the trade name Lantus XR.

"For patients requiring basal insulin, Lantus XR could positively impact hypoglycemia during the critical initiation phase, when most titration occurs, and beyond," said Professor Masato Odawara of Tokyo Medical University. "Japan-specific data show that Lantus XR patients experienced less nocturnal hypoglycemia and no increase in hypoglycemia at any time of the day. This outcome was delivered with glycemic control comparable to Lantus and is consistent with the findings in the global EDITION program in people with type 2 diabetes."

According to the MHLW, there are approximately 9.5 million people living with diabetes in Japan. "In just four months, Sanofi's next generation basal insulin has been granted marketing authorization by three major regulatory authorities," said Pierre Chancel, Senior Vice President, Head of Global Diabetes, Sanofi. "This first approval in Asia adds to the momentum of an active launch year, and it highlights our commitment to improving diabetes care worldwide."

The MHLW decision is based on the results of the EDITION Phase III study program, an extensive series of studies evaluating the efficacy and safety of Toujeo/Lantus XR compared with Lantus in more than 3,500 adults with type 1 or type 2 diabetes who were uncontrolled on their current therapy. The EDITION program established the favorable Toujeo/Lantus XR

efficacy and safety profile and included the EDITION JP 1 and JP 2 studies, which involved over 450 Japanese people with type 1 or type 2 diabetes.

Toujeo is now available in the US, Germany, Denmark and the Netherlands and has been registered in Australia. The product will become available in other countries in the coming months.