



Sanofi's New Basal Insulin Lantus[®] XR, Known as Toujeo[®] in the U.S. and Europe, Approved in Japan for the Treatment of Diabetes Mellitus

Paris, France - July 3, 2015 - [Sanofi](#) announced today that the Ministry of Health, Labor and Welfare (MHLW) in Japan 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 U.S. 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.¹

"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,²⁻⁷ 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,^{6, 7} which involved over 450 Japanese people with type 1 or type 2 diabetes.

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

About Toujeo / Lantus XR

Despite basal insulin being a cornerstone treatment for diabetes for decades, significant unmet medical needs remain a reality, with approximately half of patients on treatment not reaching their blood sugar level targets.⁸⁻¹³ In addition, optimal insulin dose is often not reached during initiation or maintenance phase. Toujeo / Lantus XR is a next-generation, once-daily basal insulin based on a broadly-used molecule (insulin glargine) with a well-established benefit-risk profile.¹⁴ Its compact subcutaneous depot leads to more stable and more prolonged pharmacokinetic/pharmacodynamic (PK/PD) profiles.¹⁵⁻¹⁷ The approved brand name for insulin glargine (rDNA origin) injection 300 U/mL in countries other than Japan is Toujeo; its brand name in Japan is Lantus XR. Toujeo



has been approved by the U.S. Food and Drug Administration (FDA), the European Commission and Health Canada, and is under review by other regulatory authorities around the world.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: [SAN](#)) and in New York (NYSE: [SNY](#)).

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Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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