Toujeo® Approved in the European Union for the Treatment of Diabetes in Adults

– New basal insulin demonstrated glycemic control with less confirmed hypoglycemia –

Paris, France – April 28, 2015 – Sanofi announced today that the European Commission has granted marketing authorization in Europe for Toujeo® (insulin glargine [rDNA origin] injection, 300 U/mL), a next-generation 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 Pierre Chancel, Senior Vice-President, 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.[1-6]

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.[7] 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.[8-10]

"Many people living with diabetes and requiring insulin are still not achieving adequate blood sugar control," said Professor Robert Ritzel, Head of the Clinic of Endocrinology, Diabetology and Addiction Medicine, Klinikum Schwabing, Städtisches Klinikum München 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 U.S. Food and Drug Administration (FDA) and is under review by other regulatory authorities around the world.

About Toujeo

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.[11-16] In addition, optimal insulin dose is often not reached during initiation

or maintenance phase. Toujeo is a next-generation, once-daily basal insulin based on a broadly-used molecule (insulin glargine) with a well-established benefit-risk profile.[17] Its compact subcutaneous depot leads to more stable and more prolonged pharmacokinetic/pharmacodynamic (PK/PD) profiles.[8-10]

Results from the EDITION clinical trials demonstrated that glycemic control with Toujeo was comparable to Lantus. The incidence of confirmed hypoglycemia (at any time of the day and nocturnal) was lower in patients treated with Toujeo compared to Lantus-treated patients, in patients with type 2 diabetes treated in combination with either non-insulin anti-hyperglycemic medicinal product or mealtime insulin. The superiority of Toujeo over Lantus in lowering the risk of confirmed nocturnal hypoglycemia was shown in patients with type 2 diabetes treated with basal insulin in combination with either non-insulin anti-hyperglycemic medicinal product (18% risk reduction) or mealtime insulin (21% risk reduction) during the period from week 9 to end of study period. Overall, these effects on hypoglycemia risk were consistently observed whatever the age, gender, BMI and duration of diabetes (<10 years and ≥10 years) in Toujeo-treated patients compared Lantus-treated patients. In patients with type 1 diabetes, the incidence of hypoglycaemia was similar in patients treated with Toujeo compared to Lantus-treated patients.[18]

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services, and devices including blood glucose monitoring systems. Sanofi markets injectable, inhaled and oral medications for people with type 1 or type 2 diabetes.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: 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).

References

1. Riddle MC, et al. Diabetes Care. 2014;37(10):2755-62. DOI: 10.2337/dc14-0991.
2. Yki-Järvinen H, et al. Diabetes Care. 2014;37(12):3235-43. DOI: 10.2337/dc14-0990.
3. Bolli GB, et al. Diabetes Obes Metab. 2015:epub ahead of print. DOI: 10.1111/dom.12438.
4. Home P, et al. Oral presentation abstract #148 presented at EASD, Vienna, September 15–19, 2014. Available from http://www.easdvirtualmeeting.org/resources/16864. Date accessed: April 2015.
5. Matsuhisa M, et al. ePoster abstract #975 presented at EASD, Vienna, September 15–19, 2014. Available from http://www.easdvirtualmeeting.org/resources/17806. Date accessed: April 2015.
6. Terauchi Y, et al. ePoster abstract #976 presented at EASD, Vienna, September 15–19, 2014. Available from http://www.easdvirtualmeeting.org/resources/17807. Date accessed: April 2015.
7. Ritzel R, et al. ePoster abstract #963 presented at EASD, Vienna, September 15–19, 2014. Available from http://www.easdvirtualmeeting.org/resources/18908. Date accessed: April 2015.
8. Steinstraesser A, et al. Diabetes Obes Metab. 2014;16(9):873-6. DOI: 10.1111/dom.12283.
9. Becker RHA, et al. Diabetes Care. 2015;38(4):637-43. DOI: 10.2337/dc14-0006.
10. Shiramoto M, et al. Diabetes Obes Metab. 2015;17(3):254-60. DOI: 10.1111/dom.12415.
11. Banegas JR, et al. Eur Heart J. 2011;32(17):2143-52. DOI: 10.1093/eurheartj/ehr080.
12. Stark Casagrande S, et al. Diabetes Care. 2013;36(8):2271-9. DOI: 10.2337/dc12-2258.
13. Chan JCN, et al. Diabetes Care. 2009;32(2):227-33. DOI: 10.2337/dc08-0435.
14. Choi YJ, et al. Diabetes Care. 2009;32(11):2016-20. DOI: 10.2337/dc08-2228.
15. Steinberg BA, et al. American Heart Journal. 2008;156(4):719-27. DOI: 10.1016/j.ahj.2008.05.020.
16. Vouri SM, et al. Journal of managed care pharmacy : JMCP. 2011;17(4):304-12.
17. Gerstein HC, et al. N Engl J Med. 2012;367(4):319-28. DOI: 10.1056/NEJMoa1203858.
18. Toujeo® EU Summary of Product Characteristics, 2015.

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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