Toujeo® Receives Positive Opinion from the European Regulatory Authorities

Paris, France – February 27, 2015 – Sanofi announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending the approval of Toujeo® (insulin glargine [rDNA origin] injection, 300 U/mL), a next-generation basal insulin for the treatment of adults with type 1 and type 2 diabetes. 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.[1-3]

"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 Pierre Chancel, Senior Vice President, 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.[4-9] 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 both at any time of the day and night-time compared with Lantus.[10]

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 U.S. 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.

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. [1-3]

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 the new 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, 2013. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Contacts:

Media Relations
Jack Cox
Tel.: + (33) 1 53 77 46 46
mr@sanofi.com

Investor Relations
Sébastien Martel
Tel.: + (33) 1 53 77 45 45
ir@sanofi.com

Global Diabetes Communications
Tilmann Kiessling
Mobile: +(49) 17 26 15 92 91
tilmann.kiessling@sanofi.com