



FDA Accepts Sanofi's New Drug Application for Basal Insulin Toujeo®

– Toujeo dossier already accepted by EMA –

Paris, France – July 8, 2014 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for Toujeo® (insulin glargine [rDNA origin] injection, 300 U/mL), an investigational basal insulin. The acceptance of the NDA follows the acceptance of the marketing authorization dossier for Toujeo by the European Medicines Agency (EMA) for EU countries on May 27, 2014.

"By reaching this key milestone in the approval process, we are pleased to take another step forward with Toujeo, an investigational new basal insulin that has been evaluated in a broad range of people living with diabetes," said Pierre Chancel, Senior Vice President, Global Diabetes at Sanofi. *"With the FDA's acceptance of our submission, we are anticipating the regulatory decision for marketing authorization for Toujeo in the U.S. in the first half of 2015."*

The NDA for Toujeo is based on results from the EDITION clinical trial program, which is a worldwide and extensive series of Phase III studies evaluating the efficacy and safety of Toujeo in over 3,500 people from broad and diverse diabetes populations.

Toujeo is the trade name for insulin glargine [rDNA origin] injection, 300 U/mL; formerly abbreviated as "U300". U300 is not currently approved or licensed anywhere in the world.

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).

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 labelling 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.

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