

# Sanofi reports results of new meta-analysis reinforcing Lantus® safety profile at the World Diabetes Congress

- Analysis of all published studies further expand the evidence base on the safety of Lantus<sup>®</sup> (insulin glargine) -

Paris, France - December 7, 2011 - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today the presentation of new meta-analysis data at the World Diabetes Congress in Dubai, adding to the wealth of evidence resulting from more than 80,000 patients enrolled in clinical trials and 38 million patient years of treatment exposure to Lantus® (insulin glargine). This new meta-analysis on the relationship between diabetes and cancer risk demonstrates no increased risk in people using Lantus® (insulin glargine).<sup>1</sup>

The meta-analysis on observational studies derived from databases as well as from randomized controlled clinical trials and from a case-control study in numerous countries (such as Sweden, Germany, Scotland, England and Taiwan) assessed the risk for cancer in individuals with diabetes using different insulins.

"This important milestone highlights the need to go beyond single study reports and utilize all available data about a topic and place the findings from any single study in the context of all available information," stated Dr. Peter Boyle, the study Principal Investigator and President of the International Prevention Research Institute (IPRI), Lyon, France. "In the context of all available information, the current evidence supports that insulin glargine is associated with no increased risk of cancer as compared to other insulin therapies. These findings are reassuring for patients and their physicians."

"These new data further reinforce the growing clinical evidence supporting the safety profile of Lantus®," said Dr. Jean-Pierre Lehner, Chief Medical Officer, Sanofi. "As an ethical company dedicated to patient safety, we welcome the coherence of these new data, which reinforce the clinical profile of Lantus®, one of the most studied treatments in the management of diabetes."

## Large-scale Epidemiology Program

Sanofi has committed efforts to generate more information on whether there is any association between cancer and insulin use and to assess if there is any difference in risk between insulin glargine and other insulins. Sanofi is sponsoring a large-scale, methodologically robust epidemiology program. As agreed with European Medicines Agency (EMA) and shared with health authorities worldwide, three large studies including two retrospective cohort studies and one case-control study are currently conducted by independent investigators. Final results of the first study based on Nordic databases will be communicated to regulatory agencies by the end of 2011 and scientific presentations are expected to follow in 2012.



### **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. Sanofi markets both injectable and oral medications for people with type 1 or type 2 diabetes. Investigational compounds in the pipeline include an injectable GLP-1 agonist being studied as a single agent, in combination with basal insulin, and/or in combination with oral antidiabetic agents.

#### **About Sanofi**

Sanofi, a global and diversified 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, rare diseases, consumer healthcare, emerging markets and animal health. 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 labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products 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 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, 2010. 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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