## Sanofi-aventis welcomes the European Medicines Agency's statement on Lantus® safety

- Based on existing evidence CHMP (the EMEA's Committee for Medicinal Products for Human Use) concludes that no changes to the prescribing advice are necessary -

**Paris, France – July 23, 2009 –** Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that following the review of the available evidence on Lantus<sup>®</sup> (insulin glargine [rDNA] injection), the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) confirmed the product's safety and concluded that changes to the prescribing advice are not necessary.

The EMEA issued a press-release stating that they have re-confirmed their initial assessment, based on an in-depth review of existing evidence and of the recent publications of registry analyses in *Diabetologia*. All four registry analyses were found to have significant methodological limitations and to provide inconsistent and inconclusive results regarding a potential link between Lantus<sup>®</sup> use and an increased risk of cancer.

"This is important and reassuring information for patients receiving Lantus<sup>®</sup>. The clinical usage of Lantus<sup>®</sup> should continue unchanged", said Dr. Jean-Pierre Lehner, Chief Medical Officer, sanofi-aventis. "The review conducted by the CHMP included the analyses of the articles recently published in Diabetologia and confirmed that they do not justify new clinical recommendations to patients."

Sanofi-aventis will implement a set of actions to develop further research in this area. These actions are in line with recommendations recently made by an independent team of interdisciplinary medical experts on this subject.

Patient safety is and has always been the primary concern of sanofi-aventis. Sanofi-aventis has 80 years of experience in the development of insulins and stands behind the safety of Lantus<sup>®</sup>. Extensive data involving over 70,000 patients in clinical studies, including randomized, controlled clinical trials that represent the gold standard of evidence, and the results of post-marketing surveillance arising from 24 million patient-years of clinical experience do not indicate an association between insulin glargine and cancer.

## **About Diabetes**

Diabetes is a chronic, widespread condition in which the body does not produce or properly use insulin, the hormone needed to transport glucose (sugar) from the blood into the cells of the body for energy. More than 230 million people worldwide are living with the disease and this number is expected to rise to a staggering 350 million within 20 years. It is estimated that nearly 24 million Americans have diabetes, including an estimated 5.7 million who remain undiagnosed. At the same time, approximately 40 percent of





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those diagnosed are not achieving the blood sugar control target of HbA1c <7 percent recommended by the ADA. The HbA1c test measures average blood glucose levels over the past two- to three-month period.

## About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis 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 product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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-aventis' 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-aventis, 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 EMEA, 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 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 as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forwardlooking information or statements.