

## **Expert Statement Issued about Lantus® Following Recent Publications in *Diabetologia***

**- Leading international experts conclude that these analyses present inconclusive and conflicting data -**

**Bridgewater, NJ – July 15, 2009** – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today the release of an Expert Statement by a multidisciplinary board of renowned international experts following an in-depth assessment of the recent publications of registry analyses with Lantus® (insulin glargine [rDNA] injection) in *Diabetologia*. This board of international specialists in the field of endocrinology, oncology and epidemiology came to the conclusion, that all four manuscripts have significant methodological limitations and shortcomings, and that they provide inconsistent and inconclusive results regarding a potential link between insulin glargine use and an increased risk of cancer.

*“Regarding the merits of the published data, we agreed that all four published manuscripts have significant methodological limitations and shortcomings,”* said Professor Matthew Riddle, Professor of Medicine, Diabetes Section Head, Division of Endocrinology/Diabetes/Clinical Nutrition, Oregon Health Sciences University, Portland, OR, USA. *“The nature of these limitations and their potential magnitude are such that, individually or in aggregate, these studies provide inconsistent and inconclusive results which do not justify new clinical recommendations to patients.”*

This statement, signed by 14 international experts following their independent, rigorous and thorough review of the published data, comes in the midst of a wave of recent releases from Health Authorities around the globe, such as the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), as well as patient and scientific associations such as the American Diabetes Association (ADA), the American Association of Clinical Endocrinologists (AACE), the International Diabetes Federation (IDF) cautioning against over-interpretation of and over reaction to these data. The limitations of these studies were also highlighted by the authors of each publication and by EASD (European Association for the Study of Diabetes). The recommendation of experts and regulatory bodies converged to say that no definitive conclusions can be drawn at this stage.

The experts proposed a set of actions to be implemented by the company and by independent experts or professional associations that they believe will lead to a clear and definite conclusion on this situation. These recommendations are the matter of the Expert Statement that can be read on: [www.sanofi-aventis.com/minisites/breaking-news/accueil/asp](http://www.sanofi-aventis.com/minisites/breaking-news/accueil/asp).

*“This position from leading world experts is consistent with previous assessments of the published analyses. What we know about the safety of Lantus® comes from a robust clinical program that includes prospective, randomized clinical trials, supported by solid post-marketing surveillance*

observations,” said Dr. Jean-Pierre Lehner, Chief Medical Officer of sanofi-aventis. “We are moving forward confidently with the external scientific and medical experts and health authorities toward next steps to resolve this controversy.”

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®. 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 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 forward-looking information or statements.*

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