

## Improved Outcomes for Patients Treated with Lantus® and Apidra® Regimen Compared with Sliding Scale Insulin

- Study Results Presented at American Diabetes Association's 70<sup>th</sup> Annual Scientific Sessions -

**Paris, France – June 25, 2010** – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that results from the Randomized Study of Basal Bolus Insulin Therapy in the Inpatient Management of Patients with Type 2 Diabetes Undergoing General Surgery (RABBIT-2 Surgery) found that treatment with a basal-bolus regimen that included Lantus® (insulin glargine [rDNA origin] injection) once-daily and Apidra® (insulin glulisine [rDNA origin] injection) before meals improved glycemic control and reduced hospital complications, compared to “sliding scale” insulin (SSI) in general surgery patients with type 2 diabetes. The study results were presented at the American Diabetes Association's 70<sup>th</sup> Annual Scientific Sessions.

Basal-bolus insulin regimens are designed to address hyperglycemia before it happens by providing adequate insulin to cover fasting and prandial insulin needs, while SSI regimens provide a corrective dose of insulin after the development of hyperglycemia has occurred.

*“Hyperglycemia in hospitalized patients is a common and costly health care problem for patients living with type 2 diabetes,”* said Guillermo E. Umpierrez, MD, Professor of Medicine, Division of Endocrinology, Metabolism and Lipids, Emory University School of Medicine and lead author of this investigator-sponsored study. *“This study indicates that a basal-bolus insulin regimen consisting of Lantus® and Apidra® may be an effective insulin regimen in the hospital management of general surgery patients with type 2 diabetes.”*

The primary endpoint is glycemic control as measured by differences in daily blood glucose (BG) levels and the secondary endpoint is a composite of postoperative complications including wound infection, pneumonia, respiratory failure, acute renal failure, and bacteremia. A blood glucose of < 70 mg/dl was reported in 23.1% of patients in the Lantus® and Apidra® group versus 4.7% of patients in the SSI group ( $p < 0.001$ ), but there were no significant differences in the frequency of severe hypoglycaemia (blood glucose < 40 mg/dl) between groups ( $p = 0.057$ ). Difference between groups in the frequency of the composite outcome including wound infection, pneumonia, bacteremia, respiratory failure, and acute renal failure were higher in the SSI group (24.3%) than in Lantus® and Apidra® basal-bolus group (8.6%),  $p = 0.003$ .

## RABBIT-2 Surgery Study Results

This randomized multicenter trial compared the efficacy and safety of Lantus® and Apidra® in a basal-bolus regimen to SSI in non-ICU patients undergoing general surgery. A total of 211 patients were randomized to Lantus® and Apidra® (n=104) or SSI (n=107). Baseline characteristics were comparable among the two arms: age 58±11 years, admission blood glucose (BG) 190±92 mg/dl, A1C: 7.72±2.2% with a BG between 140-400 mg/dl and a history of type 2 diabetes for greater than three months. Outcomes showed:

- The percentage of BG readings <140mg/dl were higher in the Lantus® and Apidra® group than the SSI (53±30% versus 31±28%, p<0.001)
- There was a significant difference between groups in the frequency of the composite outcome (24.3% and 8.6% in the SSI and Lantus® and Apidra® groups, respectively, p=0.003).
- Reductions in wound infection (2.9% versus 10.3%, p=0.05), non-statistically significant reduction in pneumonia (0% versus 2.8%, p=0.247), and in acute renal failure (3.8 % versus 10.3%, p=0.106) with Lantus® and Apidra® as compared with SSI
- Reductions in ICU length of stay (3.2±2 versus 1.2±0.6 days, p=0.003) were demonstrated with Lantus® and Apidra® as compared with SSI; while not statistically significant, there was a reduction in the number of post-surgical ICU admissions (19.6% versus 12.5%, p=NS) with Lantus® and Apidra® as compared with SSI
- No differences in mortality (1% versus 1%)

## 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 A1C <7 percent recommended by the ADA. The A1C test measures average blood glucose levels over the past two- to three-month period.

## About the sanofi-aventis Diabetes Division

Sanofi-aventis strives to be a 360 degree partner delivering innovative and integrated solutions for people living with diabetes. The Company currently has insulin products, including Lantus®, Apidra® and Insuman® -- Lantus® and Apidra® are also available as injection pens (Lantus® SoloSTAR® and Apidra® SoloSTAR®). Also available in some countries (outside the US) is ClikSTAR®, a reusable insulin injection pen for Lantus® or Apidra® for people with type 1 or type 2 diabetes. Following the formation of its Diabetes Division, sanofi-aventis has agreements with other companies for the development of blood glucose monitoring solutions and the potential first regenerative treatment for diabetes. Investigational compounds also in the pipeline include a once-daily injectable GLP-1 agonist as a monotherapy and in combination with Lantus® as well as a long-acting insulin analog.

## 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). For more information, please visit: [www.sanofi-aventis.com](http://www.sanofi-aventis.com).

## **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-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 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 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-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, 2009. 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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