

## **Less Glycemic Variability, Better Patient Reported Outcomes with Lantus® and Apidra® Regimen vs. Premix Analog Insulin**

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

**Paris, France – June 26, 2010** – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today results of a study which demonstrated that patients using Lantus® (insulin glargine [rDNA origin] injection) once-daily and Apidra® (insulin glulisine [rDNA origin] injection) before meals reported improved patient reported outcomes and decreased glycemic variability versus premix analog insulin. Two abstracts from this study were highlighted at the American Diabetes Association's 70<sup>th</sup> Annual Scientific Sessions (ADA).

People following a basal-bolus insulin regimen use separate injections of a basal insulin and a mealtime insulin. This regimen is designed to address hyperglycemia before it happens by providing adequate insulin to cover fasting and prandial insulin needs. A premix insulin regimen combines prandial insulin analogs and the intermediate-acting insulin, NPH, in one injection. The results of this study demonstrated that patients using a basal-bolus regimen, with Lantus® and Apidra®, reported improved outcomes and quality of life.

*"These results indicate that patients treated with a basal-bolus insulin regimen consisting of Lantus® and Apidra® demonstrate an improved quality of life and patient reported outcomes compared to those treated with premix analog insulin,"* said Donald Simonson, MD, MPH, ScD of the Endocrinology, Diabetes and Hypertension Division of Brigham and Women's Hospital in Boston, Massachusetts and principal investigator of the study.

### **About study results**

In this multicenter, randomized clinical trial conducted in 52 US centers, 388 insulin treated patients (82 Type 1 diabetes, 306 Type 2 diabetes) were randomized to open-label daily Lantus® and premeal Apidra® (Lantus® and Apidra®, n=192) or twice-daily premix 75/25 or 70/30 (premix; n=196) for 12 weeks (Period 1) and crossed to an alternate arm for 12 weeks (Period 2) while being titrated to A1C of <7%. The baseline A1C was 7.8+/-0.7%.

The study is highlighted at ADA in two separate abstracts.

### **1. Patient Satisfaction, Quality of Life and Glycemic Variability in Type 1 and 2 Diabetes: A Cross-over Trial of Insulin Glargine + Glulisine versus Premix Analog Insulin**

Abstract Number 2163-PO demonstrated that more patients treated with Lantus<sup>®</sup> and Apidra<sup>®</sup> achieved greater satisfaction, improved quality of life, better glycemic control and less variability, without increased risk of hypoglycemia or other adverse events versus premix analog insulin.

Outcomes showed:

- Reductions in mean A1C with Lantus<sup>®</sup> and Apidra<sup>®</sup> ( $-0.53 \pm 0.10\%$ ) versus premix ( $-0.2 \pm 0.10\%$ ) for Period 1 ( $p < 0.0001$ ) and  $-0.25 \pm 0.10\%$  versus  $+0.10 \pm 0.10\%$  for Period 2 ( $p < 0.0001$ ), respectively.
- 55% of Lantus<sup>®</sup> and Apidra<sup>®</sup> patients reached A1C < 7% versus 31% for premix ( $p < 0.0001$ ) for Period 1, with no differences in serious adverse events (5.4 versus 4.9%,  $p = \text{NS}$ ) or hypoglycemia.
- Patient Satisfaction Net Benefit scale (0-100) improved from 51.1 to  $60.5 \pm 1.2$  for Lantus<sup>®</sup> and Apidra<sup>®</sup>, but worsened to  $45.4 \pm 1.2$  for premix ( $p < 0.0001$ ).
- Overall quality of life was improved significantly for the Lantus<sup>®</sup> and Apidra<sup>®</sup> regimen versus premix ( $p < 0.001$ ).

### **2. Decreased Glycemic Variability during Insulin Therapy Improves Patient-Centered Outcomes in Type 1 and Type 2 Diabetes**

Abstract Number 0001-LB demonstrated that glycemic variability, as estimated by continuous glucose monitoring (CGMS), was lower for the Lantus<sup>®</sup> and Apidra<sup>®</sup> group than the premix group, and exhibited more favorable patient reported satisfaction and perceived health. Patient satisfaction consisted of glycemic effectiveness, advocacy, preference and general satisfaction; perceived health consisted of vitality, general health and sleep. Outcomes showed:

- Continuous glucose monitoring standard deviations were lower in the Lantus<sup>®</sup> and Apidra<sup>®</sup> group compared to premix analog insulin by  $12.2 \pm 2.6$  mg/dl and, as such, more favorable patient satisfaction ( $p < 0.0001$ ) and perceived health ( $p < 0.01$ ) was exhibited.
- The statistical model estimated that, for each 10 mg/dl decrease in continuous glucose monitoring standard deviation, patient satisfaction significantly improved by  $2.2 \pm 0.5$  ( $p < 0.001$ ), Patient Satisfaction Net Benefit scale (0-100).
- The data analysis indicated that while patient satisfaction worsened for each year of insulin use by  $2.3 \pm 0.9$  ( $p < 0.01$ ), it increased by  $6.1 \pm 1.2$  for each percent decrease in A1C ( $p < 0.001$ ).

### **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<sup>®</sup>, Apidra<sup>®</sup> and Insuman<sup>®</sup> -- Lantus<sup>®</sup> and Apidra<sup>®</sup> are also available as injection pens (Lantus<sup>®</sup> SoloSTAR<sup>®</sup> and Apidra<sup>®</sup> SoloSTAR<sup>®</sup>). Also available in some countries (outside the US) is ClikSTAR<sup>®</sup>, a reusable insulin injection pen for Lantus<sup>®</sup> or Apidra<sup>®</sup> 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<sup>®</sup> 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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