FDA Approves Rapid-Acting Insulin Apidra® for Treatment of Children with Diabetes

Paris, France - October 29, 2008 – Sanofi-aventis announced today that the U.S. Food and Drug Administration (FDA) approved Apidra® (insulin glulisine [rDNA origin] injection) to improve glycemic control in children (4 years and older) with diabetes mellitus.

The approval of Apidra® for pediatric use is based upon FDA review of a 26-week, phase III, open-label, active control study of Apidra® in comparison with insulin lispro, in 572 children and adolescents (4 years and older) with type 1 diabetes.

"Sanofi-aventis is committed to providing children with diabetes, as well as their families and healthcare providers, with safe and effective treatment options to help address the challenges associated with the condition, and to help decrease the long-term risk for devastating complications of diabetes," said Michelle Baron, MD, vice president, Metabolism Medical Unit, sanofi-aventis U.S. *"We are pleased that the fast onset of action and mealtime dosing flexibility of Apidra® will now be available to children 4 years and older."*

Apidra® has a rapid onset and short duration of action and should normally be used in combination with a longer-acting or basal insulin. Apidra® can also be used in insulin infusion pump therapy for blood sugar control.

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About the Study

The approval of Apidra® for pediatric use is based upon a 26-week, phase III, open-label, active control study of Apidra® in comparison with insulin lispro in 572 children and adolescents (4 – 17 years of age) with type 1 diabetes. Study patients received insulin glulisine or lispro 0-15 minutes premeal. These patients received concomitant treatment with insulin glargine once daily or NPH twice daily as basal insulin. The majority of the patients received insulin glargine as part of their basal-prandial regimen (69.7% and 72% in the Apidra® and insulin lispro treated groups, respectively).

The study compared the efficacy of Apidra® to insulin lispro in terms of change in glycohemoglobin (HBA1c), which is the amount of sugar bound to hemoglobin in the blood. The change in HBA1c from baseline to endpoint for Apidra® and insulin lispro were similar. The mean HBA1c change in the Apidra® population was +0.10% (± 0.08) and +0.16% (± 0.07) in the lispro group. The difference between the two treatments for this measure was -0.06%, or almost zero, with a 95% confidence interval of (-0.24; 0.12). HbA1c at baseline was 8.20% (±1.05) in the glulisine group and 8.17% (±1.02) in the lispro group; HbA1c at endpoint was 8.31% (±1.37) in the glulisine group and 8.37% (±1.32) in the lispro group. Postprandial glycemic control, as assessed by the self-monitored blood glucose values and blood glucose excursions, was similar in both treatment groups at endpoint.

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Because health matters

No noteworthy differences existed between treatment groups in the number of study patients reporting hypoglycemia, which is the most common adverse reaction of insulin therapy. This included hypoglycemia reported as a serious adverse reaction, which occurred in 7.2 percent of study patients in the glulisine group and 8.1 percent of those in the lispro group.

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. In type 1 diabetes, the immune system destroys the insulin-producing beta cells of the pancreas that regulate blood glucose. Since the pancreas can no longer produce insulin, people with type 1 diabetes require daily injections of insulin for their entire lives.

The International Diabetes Foundation estimates the global number of children 14 years of age and younger with type 1 diabetes to be 440,000, with 70,000 newly diagnosed cases each year. In the United States, type 1 diabetes is the most common type of diabetes in children, with approximately 176,500 people under 20 years of age affected by the disease. Approximately one out of every 400 to 600 American children and adolescents has type 1 diabetes.

About APIDRA® (insulin glulisine [rDNA origin])

APIDRA® is a rapid-acting insulin analog with a unique zinc-free molecular structure that maintains a rapid onset and a short duration of action, indicated for adults, adolescents and children with diabetes. APIDRA® offers patients mealtime dosing flexibility—it can be taken shortly (0-15 min) before or soon after the meal. APIDRA® is also flexible for use in a wide range of patients from lean to obese. APIDRA® is the logical partner to LANTUS® once prandial insulin is required.

About LANTUS® (insulin glargine [rDNA origin])

LANTUS® is indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia and for adult and pediatric patients (6 years and older) with type 1 diabetes mellitus. LANTUS® demonstrates a peakless and sustained concentration/time profile over 24 hours thus reducing the risk of hypoglycemia and allowing a constant and high efficacy over 24h with one single daily injection. LANTUS® is the number one prescribed insulin worldwide.

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 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 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, 2007. 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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