Abstract 1791-P

**Insulin Glulisine API**DRA® **efficacy in the treatment of children and adolescents with type 1 diabetes**

- A new study comparing efficacy and safety of API**DRA**® and insulin Lispro as part of a basal-bolus regimen -

**Paris, France – June 7, 2008** – Sanofi-aventis announced today that API**DRA**® was shown to be non inferior to insulin lispro in term of efficacy with a similar safety as part of a basal-bolus regimen in children and adolescents (from 4 to 17 years old) with type 1 diabetes using insulin glargine (LANTUS®) once-daily or NPH twice-daily as basal insulin. A higher number of patients, more particularly adolescents, reached their ADA age-specific HbA1c target with API**DRA**® compared to Lispro. The results were released during the 68th scientific session of ADA in San Francisco (1).

The results of the new randomized, parallel-group, non-inferiority study demonstrated the similar change from baseline in HbA1c (%) for API**DRA**® and Lispro (adjusted mean change 0.10 vs 0.16%, between-treatment difference (-0.06, 95% CI: [-0.24; 0.12]). Moreover, overall, the number of patients achieving their ADA age specific HbA1c target (>7.5 & < 8.5% for children <6 years, <8 % for those between 6 and 12 and <7.5% for adolescents between 13 and 17) was higher at endpoint with API**DRA**® vs Lispro with 38% vs 32% (p<0.038), difference was even more pronounced in adolescents (13-17 years) with 31% vs 21% (p<0.025).

In addition API**DRA**® is well tolerated in this population with a safety profile similar to that of Lispro and in particular with a similar monthly rate per patients of symptomatic & severe hypoglycemias (3.10 vs 2.91 and 0.06 vs 0.07 events/patients-month respectively, for the time period from month 4 to treatment end).

The efficacy and safety of API**DRA**® is the confirmed option to be used with once-daily basal insulin LANTUS® in the basal-bolus regimen. Moreover, LANTUS® SoloSTAR® and API**DRA**® SoloSTAR® being the safe, reliable and accurate devices for people with diabetes contributes to this choice.

**About the study**

The aim of this 26-week multicenter, open randomized, parallel-group, non-inferiority study was to compare the efficacy and safety of API**DRA**® and Lispro given 0-15 min pre-meal in children and adolescent with type 1 diabetes treated with LANTUS® once-daily or NPH twice-daily as basal insulin.

The results of the study demonstrate that the HbA1c change for API**DRA**® and Lispro group was similar (adjusted mean change 0.10 vs 0.16%, between-treatment difference (-0.06, 95% CI: [-0.24; 0.12], pre-specified non-inferiority margin: 0.4%). Significantly more patients using API**DRA**® vs Lispro achieved their ADA age-specific A1c targets at endpoint (38.4% vs 32.0%, p=0.0386). The difference was most pronounced in adolescents (13-17 years) with 31.1% vs 21.1% of subjects achieving A1c target <7.5% at endpoint (p=0.0251).

Safety was similar for API**DRA**® vs Lispro regarding the frequency and type of adverse events, including hypoglycaemia reported as adverse events (7.2% vs 8.1% of patients) and regarding the monthly rate of severe and symptomatic hypoglycaemia/per patient from month 4 to endpoint (0.06 vs 0.07 and 3.10 vs 2.91 events/patient-month, respectively).
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 adult patients with type 1 and type 2 diabetes. APIDRA® offers patients mealtime dosing flexibility—it can be taken within 15 minutes before or soon after meal (within 20 minutes after starting a meal). APIDRA® is also flexible for use in wide range of patients from lean to obese.

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 hyperglycaemia and for adult and paediatric patients (6 years of age and older) with type 1 diabetes mellitus. LANTUS® demonstrates a consistent slow, prolonged absorption and a relatively constant concentration/time profile over 24 hours. LANTUS® is the number one prescribed insulin worldwide.

About SoloSTAR®

SoloSTAR® is a new, easy-to-use disposable pen for administration of LANTUS® and APIDRA®. SoloSTAR® allows administering doses from 1 up to 80 units, in one unit increments, in one injection. SoloSTAR® offers a 25% greater maximum capacity than other disposable insulin pens, up to 80 units of insulin in one injection.

SoloSTAR uses a simple, intuitive design with an easy-to-read display, and requires only a few steps to use it properly. SoloSTAR® is small, discreet and eliminates the need for the patient to change insulin cartridges. Easy-to-use and easy-to-inject, SoloSTAR® reduces the injection force by 30% or more in comparison to other most broadly available pens in its class.

A recent survey of LANTUS® SoloSTAR® use in everyday clinical practice, involving more than 2000 people with diabetes (16% with manual dexterity problems and 15% with poor eyesight not corrected by glasses) showed that more than 95% of participants declared to be “satisfied” or “very satisfied” with using SoloSTAR® to inject insulin, irrespective of diabetes type or previous device experience.

LANTUS® SoloSTAR® and APIDRA® SoloSTAR® were approved by the EMEA in September 2006; LANTUS® SoloSTAR® was approved by the FDA in April 2007. LANTUS® SoloSTAR® and APIDRA® SoloSTAR® are launched in France, UK, Italy, Spain, Germany, Netherlands, Slovakia, Slovenia, Sweden, Norway, Iceland, Poland, Austria, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Australia, Lithuania, Lebanon, South Africa, and Switzerland. LANTUS® SoloSTAR® is launched in the US, Canada and India. The preparation for launches in other countries is planned during 2008.

The Chicago Athenaeum Museum of Architecture and Design awarded a 2007 GOOD DESIGN™ Award for the new SoloSTAR® disposable insulin injection pen for people with type 1 and type 2 diabetes. The Museum’s historic GOOD DESIGN program was founded in Chicago in 1950 by Edgar J.Kaufmann, Jr. with the participation of some of America’s most important designers. Every year the jury meets in New York and select products and graphics worthy of the GOOD DESIGN Award for design distinction. GOOD DESIGN remains the oldest and most important Awards program worldwide.

About sanofi-aventis’ pen portfolio

Sanofi-aventis having 85 years of innovation in the diabetes is committed to offering people with diabetes an integrated system of insulin products and delivery devices. In addition to the SoloSTAR®, the pen portfolio available for LANTUS® and APIDRA® includes the OptiSet® disposable pen, the OptiClik® and OptiPen® Pro reusable pens, and the Autopen™ 24 from Owen Mumford.
About Diabetes

Diabetes is a chronic, progressive widespread disease in which the body reduces or does not produce or properly use insulin – the hormone needed to convert glucose (sugar) into energy. More than 240 million people worldwide are living with the disease. It is estimated that near 250 million people worldwide have diabetes, the number is expected to reach some 380 million within 20 years. It is estimated more than 20 million Americans have diabetes, including an estimated 6.2 million who remain undiagnosed. At the same time, approximately half of those diagnosed are not achieving the general blood sugar control standard of A1C <7% recommended by the American Diabetes Association and the European Association for the Study of Diabetes (ADA/EASD). The A1C test reflects average blood glucose levels over a two- to three-month period.

Without proper insulin production and action, glucose remains in the blood, leading to chronic hyperglycaemia (raised blood sugar). This can result in short and long-term complications, many of which, if not prevented and left untreated, can be fatal. All have the potential to reduce the quality of life of people with diabetes and their families.

The most common long-term complications are:

- Diabetic nephropathy (kidney disease), which may result in total kidney failure and in the need for dialysis or kidney transplant.
- Diabetic eye disease (retinopathy and macular oedema), damage to the retina of the eye which can lead to vision loss.
- Diabetic neuropathy (nerve disease), which can ultimately lead to ulceration and amputation of the feet and lower limbs.
- Cardiovascular disease, which affects the heart and blood vessels and may cause fatal complications such as coronary heart disease (leading to a heart attack) and stroke.

Diabetes is the fourth leading cause of death by disease globally. Every year, 3.8 million people die from diabetes-related causes.

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, 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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References:
1. A.Phiolotheou at all. Efficacy and safety of insulin glulisine versus insulin lispro as part of a basal-bolus insulin regimen in children and adolescents with type 1 diabetes. Abstract 1791-P