[Abstract Number 467-P]

Study Shows Lantus® Helped People Living with Type 2 Diabetes Reach the ADA's Recommended Target for Blood Sugar Control

New data presented at the ADA's Annual Scientific Sessions demonstrated the value of beginning insulin promptly when glycemic targets are not achieved with diet, exercise and oral medications alone

San Francisco, June 7, 2008 – Results from a new study presented at the American Diabetes Association's (ADA) 68th Annual Scientific Sessions reinforce the importance of promptly initiating insulin treatment when patients with type 2 diabetes are unable to achieve recommended glycemic targets with diet, exercise and oral diabetes medications alone. In the TULIP (**T**esting the **U**sefulness of **L**antus® when **I**nitiated **P**romptly in patients with type 2 diabetes) clinical study, 66 percent of patients who began treatment with the long-acting, basal insulin Lantus® (insulin glargine [rDNA origin] injection) achieved A1C <7%, the ADA's recommended target for glycemic control, while only 38 percent of patients from the lifestyle management arm were able to achieve the recommended target levels.

In an effort to help guide treatment decisions, the ADA and European Association for the Study of Diabetes (EASD) developed a Consensus Algorithm for Type 2 Diabetes that calls for healthcare providers and diabetes patients to initiate insulin therapy when A1C <7% is not achieved with oral medications and lifestyle management alone. However, physicians typically wait for A1C to approach 9% before adding insulin. In general, every percentage point drop in A1C blood test results (e.g., from 8.0% to 7.0%) reduces the risk of microvascular complications (eye, kidney, and nerve diseases) by 40%.

The most common side effect of any insulin, including Lantus®, is hypoglycemia, which may be serious. In the Lantus® arm of the TULIP trial, there were 4.2±6.6 ($p<0.0001$) cases of symptomatic, 0.7±2.1 ($p=0.0011$) cases of nocturnal and 0.04±0.35 ($p=0.147$) cases of severe hypoglycemia events reported per patient year. However, no patients dropped out of the trial due to hypoglycaemia.

"When glycemic targets are not achieved with diet, exercise and oral medications given at maximum tolerated dose, patients with type 2 diabetes have reached a critical moment in the lifecycle of their condition," said Andre Grimaldi, MD, Professor Diabetes Department Head, Pitié-

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Salpêtrière Hospital, Paris, France. “The results observed in TULIP demonstrate the value of following the ADA/EASD treatment recommendations by initiating basal insulin therapy in a timely manner.”

About the TULIP Study

TULIP is a 9-month, 12-visit, open-label, multinational, multicenter, randomized study to evaluate starting Lantus® or intensifying lifestyle management in type 2 diabetes patients aged 40-75 years, body mass index (BMI) 24-35 kg/m^2 and A1C 7-8%, treated with maximum doses of metformin and sulfonylurea for ≥2 years. Lantus® was injected once-daily and titrated to capillary fasting blood glucose 70-100 mg/dL. In the lifestyle management arm, dietary and physical activity counseling recommended stable weight for people with BMI<27 kg/m^2 or weight loss of 3 kg for patients with BMI ≥27 kg/m^2. 215 patients were randomized to Lantus® (n=106) or lifestyle management (n=109).

The primary objective was the percentage of patients achieving A1C <7% at endpoint. Secondary endpoints included changes in A1C and fasting plasma glucose (FPG), and hypoglycemia incidence.

211 (52.6% male) patients were randomized and treated; mean (±standard deviation) age 60.7±7.9 years, weight 84.5±13.1 kg, BMI 29.9±3.5 kg/m^2 and A1C 7.6±0.4%. More patients reached A1c <7% (66 vs 38%; p<0.0001) or <6.5% (34 vs 11%; p<0.0001) with Lantus® versus lifestyle management. In contrast to the Lantus®-treated group, the lifestyle management-treated group showed a decrease in weight (+0.9±2.9 vs -2.5±3.2 kg; p<0.0001) as well as the expected lower hypoglycemia.

Results for hypoglycemia, A1C, FPG and weight are shown in the table.

A1C, FPG, body weight, insulin dose and hypoglycemia

		Lantus® (n=103)	**LM** (n=108)	**p**
% of patients with A1C at endpoint	<7% at endpoint; <6.5% at endpoint	66; 34	38; 11	<0.0001; <0.0001
A1C (%)	Baseline; Endpoint; Change	7.6±0.3; 6.8±0.7; -0.8±0.7	7.5±0.4; 7.3±0.9; -0.2±0.9	<0.0001*
FPG (mg/dL)	Baseline; Endpoint; Change	170±34; 122±33; -50±47	167±27; 161±41; -5±39	<0.0001*
Weight (kg)	Baseline; Endpoint; Change	85.0±12.5; 86.0±13.4; +0.91±2.9	84.0±13.7; 81.5±13.5; -2.5±3.2	<0.0001*
Daily Lantus® dose (U/kg)	Starting insulin dose; Endpoint	0.12±0.05; 0.27±0.15	n/a; n/a	n/a
Hypoglycemia (events patient per year)	Symptomatic; Nocturnal; Severe	4.2±6.6; 0.7±2.1; 0.04±0.35	2.0±7.8; 0.3±2.1; 0.00±0.00	<0.0001; 0.0011; 0.147

Results are given for all randomized and treated patients; 4 patients (Lantus®, 3; LM, 1) were randomized but not treated. Results are means ± standard deviation; *p value for between-group difference in baseline to endpoint change; FPG=fasting plasma glucose; LM=lifestyle management; n/a=not applicable

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. This number is expected to rise to a staggering 350 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 43% of those diagnosed are not achieving the blood sugar control target of A1C <7% recommended by the American Diabetes Association (ADA).

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).

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