Abstract #'s 0889-P and 0890-P

Results of Two Head-to-Head Studies Demonstrated Long-Acting Insulin Lantus® Lowered Free Fatty Acid Levels Equal to or Better Than Thiazolidinediones

Bridgewater, NJ - June 23, 2007 - Results from two new head-to-head studies showed that when added to metformin and/or a sulfonylurea, the once-a-day, long-acting insulin Lantus® (insulin glargine [rDNA origin] injection), significantly reduced free fatty acid levels in patients with type 2 diabetes compared to pioglitazone and had comparable effects to rosiglitazone. These results were presented at the American Diabetes Association's (ADA) 67th Annual Scientific Sessions.

Free fatty acids are released in the bloodstream during the breakdown of fat. High levels of free fatty acids have been linked to a number of serious complications, including insulin resistance. Since people with diabetes have naturally higher levels of free fatty acids, managing these levels effectively is an important component of diabetes treatment.

"High levels of free fatty acid have been shown to affect the regulation of glucose production by the liver and also may impact beta cell function in the pancreas, where insulin is secreted," said Julio Rosenstock, MD, Director of Dallas Diabetes and Endocrine Center at Medical City and also a Clinical Professor of Medicine, University of Texas Southwestern Medical School, Dallas, Texas. "Lipotoxicity generated by the elevated free fatty acid levels, contributes to glucose dysregulation and insulin resistance and plays a major role in type 2 diabetes."

In the first analysis (Change in Lipid Variables With Insulin Glargine (GLAR) vs Pioglitazone (PIO) Added to a Sulfonylurea (SU) or Metformin (MET) - Abstract # 0890-P), which examined the benefits of add-on therapy with Lantus® or pioglitazone in patients inadequately controlled on metformin or a sulfonylurea, the free fatty acid decreases seen with Lantus® were significantly greater than with pioglitazone (week 24: -0.19±0.02 versus -0.13 ±0.02mmol/l, P=0.03, week 48: -0.23±0.02 versus -0.15±0.02mmol/l, P=0.01).

"Physicians and patients face a difficult choice when glycemic control targets are not achieved with metformin or a sulfonylurea," explained lead study author Janet McGill, MD, Associate Professor of Medicine, Co-Director of the Prevention and Control Core of the Diabetes Research and Training Center, Washington University School of Medicine, St. Louis, Missouri. "This study is particularly timely, as the need for a better understanding of the metabolic affects associated with rosiglitazone, pioglitazone and Lantus® has never been greater."

The most common adverse events in this study were infections and infestations, nervous system disorders, musculoskeletal and connective tissue disorders, general disorders and administration-site conditions, and gastrointestinal disorders. Overall, hypoglycemia and severe hypoglycemia occurred more frequently with patients treated with insulin glargine as compared to those treated with pioglitazone.

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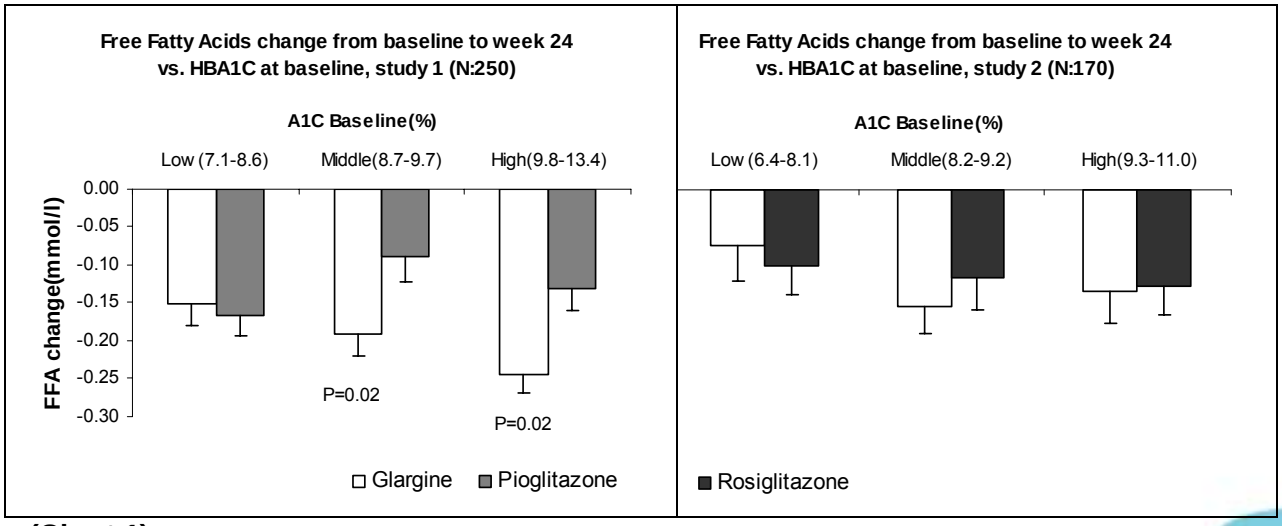
The second analysis (Free Fatty Acid (FFA) Changes with Insulin Glargine (GLAR) vs Thiazolidinediones (TZDs) According to Baseline A1C in T2DM - Abstract # 0889-P) also compared the free fatty acid-lowering effects of add-on therapy with Lantus® versus TZDs, including a comparison with rosiglitazone (study 2) as well as pioglitazone (study 1). Patients were grouped using baseline A1C (an important test that measures average blood glucose control over a two- to three-month period) scores by low, middle, and high levels (Chart 1).

After 24 weeks, mean decreases in free fatty acid were significantly greater with Lantus® versus pioglitazone in the middle (-0.19±0.03 versus -0.09±0.03mmol/L, *P*=0.02) and high (-0.24±0.03 versus -0.13±0.03mmol/L, *P*=0.02) A1C groups (chart 1, study 1).



(Chart 1)

The baseline A1C-dependent effect on free fatty acid levels may be more pronounced with Lantus®, possibly reflecting greater A1C reductions in patients with higher baseline A1C.

In the comparison between Lantus® and rosiglitazone, free fatty acid decreases were similar after 24 weeks, but decreases in triglyceride levels were significantly greater with Lantus® in the low A1C group (A1C 6.4-8.1 percent, *P*=0.006) (see chart 2). High triglycerides are one of many factors that may indicate a person is at risk for heart disease, which accounts for about 65 percent of deaths in people with diabetes.

The most common adverse events in this study were infections and infestations, nervous system disorders, musculoskeletal and connective tissue disorders, general disorders and administration-site conditions, and gastrointestinal disorders. Overall, hypoglycemia and severe hypoglycemia occurred more frequently with patients treated with insulin glargine compared to those treated with pioglitazone; however, there were no differences in hypoglycemia between the patients treated with insulin glargine and those treated with rosiglitazone.

"The benefits seen in these studies are very promising and will be examined further, as we continue to explore the cardiovascular potential of Lantus® treatment," stated Antonio Tataranni, MD, Vice President, Medical Metabolism, sanofi-aventis. "For example, the ongoing ORIGIN study will examine long-term cardiovascular outcomes in more than

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12,000 diabetic and pre-diabetic patients. The ORIGIN study is now fully enrolled and we expect its results in 2010."

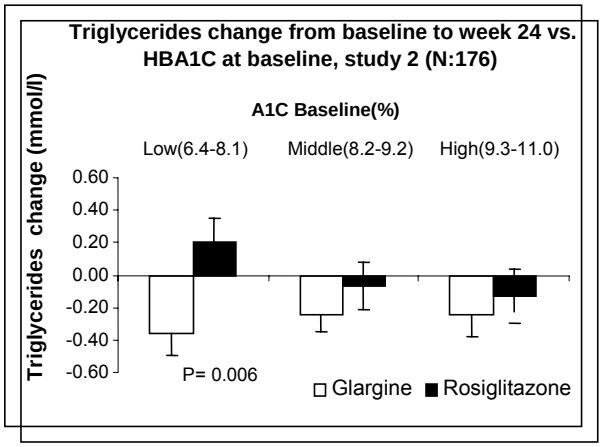
About Poster 1
(Change in Lipid Variables With Insulin Glargine (GLAR) vs Pioglitazone (PIO) Added to a Sulfonylurea (SU) or Metformin (MET) - Abstract # 0890-P)
This randomized, multicenter, 48-week, parallel-group, open label study compared the lipid changes observed with Lantus® (n=129) and pioglitazone (n=130) add-on therapy in type 2 diabetes patients inadequately controlled with ≥ 50 percent of the maximum labeled dose of a sulfonylurea or ≥ 1000mg of metformin. Free fatty acid, triglyceride and HDL changes were compared in the two groups (sulfonylurea or metformin).

After 48 weeks, A1C was decreased to a significantly greater extent in the metformin group of the glargine versus pioglitazone group (P<0.024; for the sulfonylurea at 48 weeks P=NS). Free fatty acid decreases from baseline with Lantus® were significantly greater than pioglitazone at both 24 weeks and 48 weeks for the group receiving sulfonylurea (week 24: -0.19 ±0.02 versus -0.11±0.03mmol/l, P=0.05, week 48: -0.21±0.03 versus -0.10±0.04mmol/l, P=0.03)

About Poster 2
(Free Fatty Acid (FFA) Changes with Insulin Glargine (GLAR) vs Thiazolidinediones (TZDs) According to Baseline A1C in T2DM - Abstract # 0889-P)
This analysis was based on study one and a randomized, multicenter, 24-week, parallel-group, open label study to assess free fatty acid and triglyceride changes according to baseline A1C in type 2 diabetes patients inadequately controlled on a sulfonylurea and/or metformin receiving add-on therapy with either Lantus® or rosiglitazone). The poster examines results of these pioglitazone and rosiglitazone arms as two separate studies.

In the Lantus® (n=165) versus pioglitazone (n=182) study, baseline and week 24 lipid values were available for 121 and 129 patients, respectively. Baseline A1C groups were defined as low (7.1 - 8.6 percent), middle (8.7 - 9.7 percent), and high (9.8 - 13.4 percent). In the Lantus® (n=105) versus rosiglitazone (n=112) comparison, baseline and week 24 lipid values were available for 87 and 83 patients, respectively. A1C groups at this juncture were low (6.4 - 8.1 percent), middle (8.2 - 9.2 percent) and high (9.3 - 11.0 percent).

In the Lantus®-pioglitazone study, decreases in mean±SE free fatty acid were significantly greater with Lantus® versus pioglitazone in the middle (-0.19±0.03 versus -0.09±0.03mmol/L, *P*=0.02) and high (-0.24±0.03 versus -0.13±0.03mmol/L, *P*=0.02) A1C groups. In the Lantus®-rosiglitazone comparison, free fatty acid decreases were similar with glargine and rosiglitazone. Decreases in triglycerides were similar for glargine and pioglitazone in all groups regardless of baseline A1C, and significantly greater with glargine versus rosiglitazone in the low A1C group (-0.36±0.14 versus 0.20±0.14, *P*=0.006) (see chart 2).



(Chart 2)

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About Diabetes
Diabetes is a chronic, widespread condition in which the body does not produce or properly use insulin – the hormone needed to convert glucose (sugar) into 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.[1] It is estimated more than 20 million Americans have diabetes, including an estimated 6.2 million who remain undiagnosed.[2] At the same time, approximately half of those diagnosed are not achieving the general blood sugar control standard of A1C <7 percent recommended by the American Diabetes Association (ADA).[3] The A1C test measures average blood glucose levels over a two- to three-month period.

About sanofi-aventis
Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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