News Releases

# Sanofi-aventis: Adding Lantus® to Oral Antidiabetic Drug Therapy Further Reduced Blood Sugar in Patients With Type 2 Diabetes

- Findings Presented at European Association for the Study of Diabetes (EASD) 46th Annual Meeting

PARIS, Sept. 20 /CNW/ - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today results of two studies presented at the European Association for the Study of Diabetes (EASD) 46th Annual Meeting in Stockholm, Sweden. The first pooled analysis using patient-level data from randomized clinical trials demonstrated that adding Lantus® (insulin glargine (rDNA) injection) to patients with type 2 diabetes, uncontrolled on oral antidiabetic drug therapy (OADs), was associated with a greater reduction in A1C levels and lower incidence of any hypoglycemia versus all comparators (OADs, NPH, lispro, premix).

In the second pooled analysis of clinical studies, "patients with type 2 diabetes, who used Lantus® as monotherapy or added it to one baseline oral antidiabetic agent, demonstrated a greater reduction in A1C with lower risk of hypoglycemia than those taking two OADs, with a most significant reduction when Lantus® was added to metformin alone versus other OADs (sulfonylurea alone or sulfonylurea plus metformin)," said Dr. Jack Leahy of the University of Vermont College of Medicine and principal investigator of one of the studies.

Better Efficacy and Goal Attainment Demonstrated with Insulin Glargine versus All Comparators(i)

"Efficacy and Goal Attainment with Insulin Glargine vs Comparators" (presentation number 976): This pooled analysis looked at nine clinical studies where insulin-naive patients with type 2 diabetes uncontrolled on OADs were randomized to add Lantus® (n=1,462) or comparators (OADs, NPH, lispro or premix; n=1,476) to their treatment regimen. Results showed that initiating Lantus® in patients uncontrolled on OADs was associated with better efficacy and goal attainment overall versus all comparators across the A1C continuum and when compared to OADs when baseline A1C was greater than or equal to 8.0 percent.

Outcomes showed:

- A1C reductions at week 24 were greater with Lantus® versus all comparators (p less than 0.001)
- Efficacy across A1C categories were similar for insulin comparators
- Hypoglycemia rates (any) were lower with Lantus® versus other insulin comparators (Lantus vs. NPH, p=0.032, Lantus vs. lispro, p= less than 0.001, Lantus vs. premix, p=004)
- Hypoglycemic event rates (any) were higher for Lantus versus OADs (p less than 0.001), although rates of severe hypoglycemia were similar between the two groups.

Significant Improvement in A1C Found Independent of Baseline Treatment Regimen(ii)

"Clinical Outcomes after Basal Insulin Initiation Correlate with Baseline Oral Antidiabetic Drug Therapy: A Pooled Analysis of Clinical Trial Data" (presentation number 960): This analysis included data from 11 prospective randomized controlled trials of Lantus® with or without OADs in adults with type 2 diabetes. The analysis compared patients given Lantus® (n=2,171) who were taking zero or one OAD at baseline (low use; 1.8% and 45.2%, respectively) with those taking two OADs (52.2%) and patients on metformin only (8.5%) with those on sulfonylurea only (36.5%) or metformin and sulfonylurea (49.9%) at baseline.

Outcomes showed:

- At week 24, the reduction in A1C was greatest among patients given Lantus® with low baseline OAD use (0/1 OADs) (p=0.0198) and among those who were taking Lantus and metformin only (p=0.0009)
- Patients given Lantus® with low baseline OAD use had significantly lower rates of symptomatic hypoglycemia versus those taking two OADs (p=0.0009)
- Patients given Lantus® who were taking only metformin had lower rates of hypoglycemia than those taking sulfonylurea or metformin plus sulfonylurea (p less than 0.0001) despite higher insulin doses (53 versus 37.5 versus 38.8 U)

Important Safety Information for Lantus®

Do not take Lantus® if you are allergic to insulin or any of the inactive ingredients in Lantus®.

You must test your blood sugar levels while using insulin, such as Lantus®. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made cautiously and only under medical supervision.

Do NOT dilute or mix Lantus® with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. Lantus® must only be used if the solution is clear and colorless with no particles visible. Do not share needles, insulin pens or syringes with others.

The most common side effect of insulin, including Lantus®, is low blood sugar (hypoglycemia), which may be serious. Some people may experience symptoms such as shaking, sweating, fast heartbeat, and blurred vision. Severe hypoglycemia can be dangerous and can cause harm to your heart or brain. It may cause unconsciousness, seizures, or death. Other possible side effects may include injection site reactions, including changes in fat tissue at the injection site, and allergic reactions, including itching and rash. In rare cases, some allergic reactions may be life threatening. Tell your doctor about other medicines and supplements you are taking because they can change the way insulin works. Before starting Lantus®, tell your doctor about all your medical conditions including if you have liver or kidney problems, are pregnant or planning to become pregnant, or are breast-feeding or planning to breast-feed.

Indications and Usage

Prescription Lantus® is a long-acting insulin used to treat adults with type 2 diabetes and adults and children (6 years and older) with type 1 diabetes for the control of high blood sugar. It should be taken once a day at the same time each day to lower blood glucose. Do not use Lantus® to treat diabetic ketoacidosis.

Lantus® SoloSTAR® is a disposable prefilled insulin pen.

For full prescribing information for Lantus®, please visit http://www.Lantus.com or call +1-800-633-1610.

Important Safety Information for Apidra®

Do not use Apidra® during a low blood sugar reaction (hypoglycemia) or if you are allergic to any of the ingredients in Apidra®.

You must test your blood sugar levels while using insulin, such as Apidra®. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made cautiously and only under medical supervision. Apidra® must only be used if the solution is clear and colorless with no particles visible. Do not share needles, insulin pens or syringes with others.

Apidra®, when given by injection under the skin, should not be mixed with insulins other than NPH. Do not mix Apidra with any insulin when used in the pump or for intravenous administration.

The most common side effect of insulin, including Apidra, is low blood sugar (hypoglycemia), which may be serious. Some people may experience symptoms such as shaking, sweating, fast heartbeat, and blurred vision. Severe hypoglycemia can be dangerous and can cause harm to your heart or brain. It may cause unconsciousness, seizures, or death. Other possible side effects may include low blood potassium, injection site reactions, such as changes in fat tissue at the injection site, and allergic reactions, such as itching and rash. Less common, but potentially more serious or life-threatening, is generalized allergy to insulin, including anaphylactic reactions.

Tell your doctor about other medicines and supplements you are taking because they can change the way insulin works. Before starting Apidra®, tell your doctor about all your medical conditions including if you have liver or kidney problems, are pregnant or planning to become pregnant, or are breast-feeding or planning to breast-feed.

Indications and Usage

Prescription Apidra® is for adults with type 2 diabetes or adults and children (4 years and older) with type 1 diabetes to improve blood sugar control. Apidra® is usually used with a longer-acting insulin. When used as a mealtime insulin, Apidra® should be given within 15 minutes before or within 20 minutes after starting a meal.

Apidra® SoloSTAR® is a disposable prefilled insulin pen.

For full prescribing information for Apidra®, please visit http://www.Apidra.com or call +44(0)800-633-1610.

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. It is estimated that approximately 285 million adults worldwide are living with the disease and this number is expected to rise to a staggering 438 million within 20 years(iii),(iv). It is estimated that nearly 24 million Americans have diabetes, including an estimated 5.7 million who remain undiagnosed(v) At the same time, according to NHANES data from 2003-2004, approximately 40 percent of those diagnosed with diabetes did not achieve the blood sugar control target of A1C (less than)7 percent recommended by the ADA(vi). 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®, Apidra® and Insuman® (outside the US)-- Lantus® and Apidra® are also available as injection pens (Lantus® SoloSTAR® and Apidra® SoloSTAR®). Also available in some countries (outside the US) is ClikSTAR®, a reusable insulin injection pen for Lantus® or Apidra® 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 the once-daily injectable GLP-1 agonist lixisenatide as a monotherapy and in combination with basal insulin as well as long-acting insulin analogs.

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: http://www.sanofi-aventis.com.

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(i) Banerji, M.A., "Efficacy and Goal Attainment with Insulin Glargine vs Comparators." Presented at the European Association for the Study of Diabetes 46th Annual Meeting, presentation number 976,2010.

(ii) Leahy, J. "Clinical outcomes after basal insulin initiation correlate with baseline oral antidiabetic drug therapy: a pooled analysis of clinical trial data." Presented at the Association for the Study of Diabetes 46th Annual Meeting, presentation number 960, 2010.

(iii) IDF Diabetes Atlas.Global Burden.Aug.2010/Page 1/Lines 26-27

(iv) IDF Diabetes Atlas.Global Burden.Aug.2010/Page 1/Lines 29-30

(v) CDC.DiabetesFactSheet.2007/Pg 5/Line 20)

(vi) Ford.DiabetesCare.Jan.2008/Pg 103/Table 1

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