# Sanofi Announces Positive Results from the "All to Target" Study Evaluating Two Lantus® and Apidra® Regimens versus Premixed Regimen

***- Data Presented at American Diabetes Association's 71st Annual Scientific Sessions -***

**Paris, France – June 24, 2011 –** Sanofi (EURONEXT: SAN and NYSE: SNY) announced today data from a 60-week, open-label study that compared three intensified insulin regimens added to oral therapy for uncontrolled type 2 diabetes and found that using two regimens including Lantus® (insulin glargine [rDNA origin] injection) and Apidra® (insulin glulisine [rDNA origin] injection) lowered blood glucose levels compared to premixed insulin with less hypoglycemia and improvement in diabetes-specific quality of life.

"*Optimization of insulin dosage with glargine plus a single mealtime injection of glulisine allowed more patients to reach target A1C levels than with twice-daily premixed insulin, and with less hypoglycemia*," said Matthew Riddle, MD, head of the Oregon Health and Science University Section of Diabetes and lead investigator of one of the data analyses presented at the meeting. "*These findings support a stepwise approach to addition of mealtime insulin when basal insulin with oral agents is not sufficient to maintain control*."

Three analyses of this data are being either presented or published at the American Diabetes Association's 71st Scientific Sessions in San Diego, California.

**About the "All to Target" Study**

The study was designed to evaluate glycemic control achieved by three intensified insulin regimens with two co-primary objectives: 1) to demonstrate superiority of Lantus plus up to 3 injections of mealtime Apidra versus premixed insulin, as measured by A1c<7% at week 60; and 2) to demonstrate non-inferiority of Lantus plus up to 1 injection of mealtime Apidra versus premixed insulin, based on the reduction from baseline to week 60.

Investigators compared the addition of twice-daily Novolog® (insulin aspart) Mix 70/30 (PREMIX; n=192) versus Lantus® plus up to one prandial dose of Apidra® (GLARG + 0-1; n=189) versus Lantus® with the stepwise addition of up to 3 injections of Apidra® (GLARG+ 0-3; n=191) in 572 patients with type 2 diabetes who did not achieve glycemic control with oral therapy.

The patients enrolled in the study had a mean age of 54 years and body mass index of 33.2 kg/m$^2$. They had been diagnosed with type 2 diabetes for an average of 9 years and were failing to control their diabetes despite two to three oral agents. The baseline A1C in this study was 9.4 percent after a four-week run-in. Insulin was titrated seeking fasting and pre-prandial glucose <100 mg/dL in all treatment arms.

The study results supported the non-inferiority of Lantus® plus up to 1 injection of Apidra® versus two–injections of premixed insulin, while in the Lantus® plus up to 3 injections of Apidra® arm, superiority versus premixed insulin was not shown.

Based on the secondary endpoints, the combination of Lantus® and Apidra® led to significantly larger proportions of patients achieving target A1C with statistically lower rates of hypoglycemia and significantly greater fasting plasma glucose reductions, although superiority versus premixed insulin was not achieved. The regimen consisting of a single dose of Apidra® added to Lantus® led to a greater decrease in HbA1c from baseline at week 60 (-2.30 percent versus -1.97 percent, p=0.036 NS), and a delayed and lesser need for insulin dose escalation compared to twice daily premixed insulin.

The percentage of patients who experienced treatment-emergent adverse events was similar across all treatment groups. The most common treatment-emergent adverse events (percentage of patients with events) by system, organ, class include: infections and infestations (upper respiratory infection, sinusitis, nasopharyngitis; 41.9%), musculoskeletal and connective tissue disorders (pain in extremity, back pain, musculoskeletal pain; 22.5%), nervous system disorders (hypoasthesia, dizziness, parasthesia; 17.0%) and gastrointestinal disorders (nausea, abdominal discomfort, dyspepsia; 16.8%).

The study findings are highlighted at the American Diabetes Association's Scientific Sessions in three separate abstracts.

**1. Comparison of 3 Intensified Insulin Regimens Added to Oral Therapy for Type 2 Diabetes: Twice-Daily Aspart Premixed versus Glargine plus 1 Prandial Glulisine or Stepwise Addition of Glulisine to Glargine (Riddle et al) [Abstract # 0409-PP]:** In this analysis, a significantly larger proportion of patients achieved target A1C <7 percent at week 60 on both glargine-based regimens with less hypoglycemia than with premixed insulin.

**2. Time Course of Fasting Glucose, Hypoglycemia and Body Weight during Systematic Insulin Dose Titration: BID Aspart Premixed versus Glargine +1 Prandial Glulisine or Stepwise Addition of Glulisine to Glargine in Type 2 Diabetes Uncontrolled with Oral Agents (Rosenstock et al) [Abstract # 0073-OR]:** In this analysis, body weight increased in parallel with insulin dose, however, hypoglycemia was less frequent and decreases in FPG were greater with regimens including Lantus® and Apidra® than premixed insulin, regardless of dose or duration of therapy.

**3. Patient Reported Outcomes Using Twice-Daily Insulin Aspart Premixed versus Insulin Glargine Plus 1 Prandial Insulin Glulisine or Stepwise Addition of Glulisine to Glargine in Type 2 Diabetes Uncontrolled With Oral Agents (Polonsky et al) [Abstract # 2316-PO]:** In this analysis, patient-reported outcomes were measured at baseline at, 6, 12, 24, 36, 48 and 60 weeks to assess overall quality of life (QoL), diabetes-specific quality of life (DQoL), hypoglycemic fear and adjustment to illness. While the three insulin regimens did not differentially influence overall quality of life or adjustment to disease, glargine-based regimens led to greater improvement in DQoL versus premix with less hypoglycemic fear.

## About Diabetes

Diabetes is a chronic, widespread condition characterized by high blood sugar 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. It is estimated that nearly 26 million Americans have diabetes, including an estimated 7 million who remain undiagnosed. At the same time, approximately 40 percent of those diagnosed with diabetes did not achieve the blood sugar control target of A1C <7 percent recommended by the American Diabetes Association. The A1C test measures average blood glucose levels over the past two-to-three-month period.

## About the Sanofi Diabetes Division

Sanofi strives to help people manage the complex challenges of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insight that comes from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services, and devices. Sanofi markets both injectable and oral medications for people with type 1 or type 2 diabetes. Investigational compounds in the pipeline include an injectable GLP-1 agonist being studied as a single agent, in combination with basal insulins, and/or in combination with oral antidiabetic agents.

## About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi 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 projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, 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's 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, 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 EMA, 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, the Group's ability to benefit from external growth opportunities as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2010. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

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