



## Initiation of Lantus leads to better glycemetic control at similar weight gain versus other comparators in patients with Type 2 Diabetes

*- Weight gain was lowest in patients with baseline A1C below 8 percent and in patients 65 years and older -*

*- Pooled Analysis Presented at European Association for the Study of Diabetes (EASD) 47<sup>th</sup> Annual Meeting -*

**Paris, France – September 12, 2011** – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today data that demonstrates that initiating Lantus<sup>®</sup> (insulin glargine [rDNA origin] injection) in type 2 diabetes patients leads to better glycemetic control and comparable and modest weight gain versus a comparator group consisting of other insulins, oral antidiabetics (OADs) and dietary changes. The lowest weight gain was seen in patients initiating treatment with baseline A1c levels below eight percent and in patients aged 65 and older. This data is being presented at the European Association for the Study of Diabetes (EASD) 47<sup>th</sup> Annual Meeting in Lisbon, Portugal.<sup>1</sup>

*“Weight gain is a commonly perceived effect of using insulin in type 2 diabetes,”* said Jack Leahy of the University of Vermont and lead investigator of the data presented at the meeting. *“This data demonstrates that initiation of Lantus<sup>®</sup> when A1C is less than eight percent may help to limit weight gain in this patient population.”*

A total of 2,900 patients were evaluated from nine pooled, randomized, controlled 24-week studies. In each study, Lantus<sup>®</sup> was tested against a comparator (63% other insulins, 32% OADs, 6% dietary). Weight gain was assessed by treatment, demographics, age and baseline A1C and FPG.

Weight gain with Lantus<sup>®</sup> was similar to weight gain for comparators (mean weight gain 2.2 kg vs. 2.1kg) but varied with patient baseline A1c and age. Patients with A1c below 8 percent had the lowest overall weight gain. Weight gain increased with increasing baseline A1c (Pearson correlation, glargine  $r=0.1951$ ,  $p<0.0001$ ; comparators  $r=0.2409$ ,  $p<0.0001$ ). In addition, patients aged 65 and older had the lowest weight gain; weight gain significantly decreasing as patient’s age increased (Pearson correlation, glargine  $r=-0.1625$ ,  $p<0.0001$ ; comparators  $r=-0.1215$ ,  $p<0.0001$ ).

More patients achieved A1c less than or equal to seven percent with Lantus<sup>®</sup> versus comparators (58.3% vs. 52.7%; OR=1.27;  $p=0.0017$ ), with the highest percentage of patients reaching target when glargine was initiated at the baseline A1c levels below eight percent (79.8% vs 70.4%, OR=1.76;  $p=0.0011$ ). Older patients versus younger patients treated with Lantus<sup>®</sup> were more likely to achieve A1C less than or equal to seven percent ( $P=0.0055$ ); there was no such trend for the comparator group.

Hypoglycemia (glucose confirmed  $<50$  mg/dL) occurred significantly ( $p<0.0001$ ) less often with Lantus<sup>®</sup> than the comparators, with the lowest estimate among Lantus<sup>®</sup> patients 65 years and older.



### **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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### **Reference:**

1. Lower weight gain and better outcomes in patients with type 2 diabetes starting insulin treatment when baseline A1C <8 percent: Abstract No: 670

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