Sanofi Announces Positive Phase 3 Results for Investigational New Insulin U300

- EDITION I demonstrated similar blood sugar control with fewer night-time low blood sugar events compared to Lantus® -

- Topline results of EDITION II consistent with EDITION I findings -

Paris, France – June 22, 2013 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the first phase 3 study results (EDITION I) for its investigational new insulin U300 showed equivalent blood sugar control with fewer night-time low blood sugar events compared to Lantus® (insulin glargine [rDNA origin] injection). The company also announced topline results of a second Phase 3 study (EDITION II) for new insulin U300 that also demonstrated similar blood sugar reduction while fewer patients experienced night-time low blood sugar events compared with Lantus®.

These results are from EDITION I and EDITION II respectively and are part of the EDITION Phase 3 clinical program evaluating the efficacy and safety of the investigational new insulin U300 in people with diabetes. The EDITION I data was presented at the 73rd Scientific Sessions of the American Diabetes Association.

"*To properly manage diabetes, it is critical to control blood sugar and to reduce the risk of low blood sugar events, especially at night,"* said Matthew Riddle, Professor of Medicine, Division of Endocrinology/Diabetes/Clinical Nutrition, Oregon Health and Science University, U.S., and Principal Investigator for the EDITION I study*. "I am encouraged by these findings, and look forward to the results of the full Phase 3 EDITION program, which will further reveal how this investigational basal insulin may help people living with diabetes*."

EDITION I

As the first study of the EDITION Phase 3 program, EDITION I evaluated the efficacy and safety of investigational new insulin U300, vs. Lantus® in people with type 2 diabetes using basal plus mealtime insulin. In a multicenter, open-label study 807 people were randomized (1:1) to once daily evening new insulin U300 (n=404) or Lantus® (n=403) while continuing mealtime insulin. The basal insulin was titrated to achieve fasting plasma glucose of 80-100 mg/dL. Primary endpoint was change in HbA_{1c} from baseline to month 6, and main secondary endpoint was % of people with at least 1 severe or confirmed (≤70 mg/dL) nocturnal hypoglycemic event from month 3 to month 6.

EDITION I demonstrated similar reductions in HbA_{1c} (glycated hemoglobin) from baseline (primary endpoint) between new insulin U300 and Lantus® at 6 months [least squares mean change -0.83% (0.06) in both groups; difference -0.00% (95% CI -0.11 to 0.11)] in people with type 2 diabetes who had challenging treatment needs (mean age of study participants: 60 years; duration of type 2 diabetes: 15.8 years; BMI: 36.6 kg/m^2; HbA_{1c}: 8.15 %; total insulin dose: 1.2 U/kg; basal insulin dose: 0.67 U/kg at baseline). In addition, approximately 40% of study participants with uncontrolled glycemic (blood sugar) levels despite receiving a combined therapy (oral antidiabetic agents plus

basal and prandial insulins) reached glycemic control (HbA_{1c} <7%) at month 6 both in the new insulin U300 (39.6%) and in the Lantus® arm (40.9%).

The investigational new insulin U300 was associated with a 21% reduction in severe or confirmed nocturnal hypoglycemia (low blood sugar) from month 3 to month 6. Significantly fewer patients had nocturnal (severe and/or confirmed; i.e. ≤70 mg/mL) hypoglycemia (low blood sugar) during months 3 to 6 (pre-specified main secondary endpoint: 36.1% vs. 46.0%; RR 0.79; p=0.0045) and the occurrence of any nocturnal hypoglycemic event (% of people with at least one event) during the 6-month study period was lower on new insulin U300 during the study period compared to the Lantus® group (45.3% vs. 59.7%; RR 0.76; 95% CI 0.66 to 0.87). New insulin U300 was well-tolerated in this study, with no differences in other adverse events observed from Lantus®.

The EDITION I abstract is titled: **New Insulin Glargine Formulation: Glucose Control and Hypoglycemia in People with Type 2 Diabetes Using Basal and Mealtime Insulin (EDITION I) (Riddle, MC et al) [Abstract no. 43-LB]**

EDITION II

Topline results of EDITION II are consistent with EDITION I findings. EDITION II demonstrated that investigational new insulin U300 achieved similar blood sugar reduction while fewer patients experienced night-time low blood sugar events compared with Lantus®.

EDITION II evaluated efficacy and safety of new insulin U300 in a type 2 diabetes population (811 patients) treated with basal insulin plus oral antidiabetic therapy. The full EDITION II results will be submitted for presentation at upcoming scientific meetings.

"There remains a substantial unmet need in people with diabetes taking oral medication or insulin as many of them do not reach their glycemic goals," said Pierre Chancel, Senior Vice President, Global Diabetes, Sanofi. *"With the investigational new insulin U300, we are striving to further enhance the clinical value of basal insulin, while building on the wealth of evidence of Lantus®, the world's most prescribed insulin."*

About investigational new insulin U300

Investigational new insulin U300 is a new formulation based on the glargine molecule, the biological entity of Lantus®, with its well established efficacy and safety profile. However, new insulin U300 has unique pharmacokinetic and pharmacodynamic profiles with studies demonstrating it has even flatter and more prolonged profiles than Lantus®.[1,2] New insulin U300 also offers the benefit of a smaller volume of subcutaneous injection compared with Lantus®.

About the EDITION Phase 3 Program

The EDITION program is a worldwide and comprehensive series of Phase 3 studies evaluating the efficacy and safety of new insulin U300 in broader and diverse populations of people with diabetes. The full EDITION I (basal + mealtime insulin) and EDITION II (basal Insulin + oral therapy) results are expected by the end of this year. Additionally, the following Phase 3 studies from the EDITION program are ongoing: EDITION III in insulin-naïve type 2 diabetes patients , EDITION IV in type 1 diabetes patients, EDITION JP I in Japanese type 1 diabetes patients (basal + bolus insulin) and EDITION JP II in Japanese type 2 diabetes patients (basal insulin + oral therapy).

About Diabetes

Diabetes is a chronic disease that occurs as type 1 diabetes, which is an autoimmune disease characterized by the lack of insulin (the hormone that regulates blood glucose concentrations) production by the pancreas, and type 2, a metabolic disorder in which there are two main biological defects: a deficient production of insulin and reduced ability of the body to respond to the insulin being produced. Type 1 and type 2 diabetes are characterized by an increase in blood glucose

concentrations (hyperglycemia). Over time, uncontrolled hyperglycemia leads to the macrovascular and microvascular complications of diabetes. Macrovascular complications, which affect the large blood vessels, include heart attack, stroke and peripheral vascular disease. Microvascular complications affect the small blood vessels of the eyes (retinopathy), kidney (nephropathy) and nerves (neuropathy). The global incidence of diabetes is growing at an alarming rate, with more than 371 million people worldwide living with the condition today.

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services and devices, including blood glucose monitoring systems. Sanofi markets both injectable and oral medications for people with type 1 or type 2 diabetes.

About Sanofi

Sanofi, an integrated global 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, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

References

1. Tillner J et al. Euglycemic Clamp Profile of New Insulin Glargine U300 Formulation in Patients With Type 1 Diabetes (T1DM) is Different From Glargine U100.73rd Scientific Sessions of the ADA, abstract no. 920-P
2. Dahmen R et al New Insulin Glargine U300 Formulation Evens and Prolongs Steady State PK and PD Profiles During Euglycemic Clamp in Patients With Type 1 Diabetes (T1DM)". 73rd Scientific Sessions of the ADA, abstract no. 113-OR

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 labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product 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, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding 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, 2012. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Sanofi will host a conference call for the financial community on Monday June 24, 2013, at 700 AM CST (200 PM Paris Time). The call will include results from the ongoing EDITION phase 3 program for U300 as well as a status update on the fixed-ratio combination of insulin glargine and lixisenatide.
Dial-in numbers and the audio webcast link will be accessible via www.sanofi.com.

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