Sanofi Announces New Phase 3 Results for Investigational New Insulin U300

− EDITION II trial demonstrates similar blood sugar control with fewer night-time low blood sugar events for U300 compared with Lantus® −

− EDITION III, IV and JP I studies meet primary endpoint −

Paris, France – December 3, 2013 – Sanofi announced the full results from the EDITION II study showing that investigational new insulin U300 demonstrated similar blood sugar control with 23% fewer patients experiencing night-time low blood sugar compared with Lantus® (insulin glargine [rDNA origin] injection). These results were presented today at the International Diabetes Federation 2013 World Diabetes Congress in Melbourne, Australia. The full EDITION II results are consistent with those from EDITION I.[1] Both studies were conducted in people with type 2 diabetes already using basal insulin (with mealtime insulin or oral medication).

Sanofi also announced today additional top-line results from the EDITION Phase 3 clinical program. The primary endpoint was met in the 6-month EDITION III, EDITION IV and EDITION JP I studies. Full results will be presented at scientific meetings in 2014.

"We are encouraged by these results which suggest that U300 could be a viable treatment option for a wide range of people with type 1 and type 2 diabetes." commented Pierre Chancel, Senior Vice President, Global Diabetes, Sanofi.

EDITION II Full Results

EDITION II included type 2 diabetes patients, who failed to control their blood sugar levels on previous basal insulin and oral medication, together with a long duration of disease and high body mass index (BMI). The study randomized 811 participants (1:1) to U300 (n=404) or Lantus® (n=407) once daily in the evening, while continuing oral anti-diabetics.

EDITION II met its primary endpoint by showing similar reductions in HbA1c from baseline between U300 and Lantus® at 6 months [least squares mean change -0.57% (0.09) and -0.56% (0.09), respectively; difference -0.01% (95% CI: -0.14 to +0.12)] in people with type 2 diabetes who had challenging baseline characteristics (mean age of study participants: 58.2 years; duration of type 2 diabetes: 12.6 years; BMI: 34.8 kg/m^2; HbA_{1c}: 8.24 %; basal insulin dose: 0.67 U/kg at baseline).

The percentage of participants with severe or confirmed (defined by plasma glucose ≤70 mg/dL) night-time low blood sugar levels (nocturnal hypoglycemia) from month 3 to 6 was significantly lower with U300 vs. Lantus® [21.6% vs. 27.9%; relative risk (RR) 0.77 (95% CI: 0.61 to 0.99); p=0.038]. Over the 6-month treatment period, the incidence of any nocturnal hypoglycemia (% of participants with ≥1 event) was lower with U300 vs. Lantus® [30.5% vs. 41.6%; RR 0.73 (95% CI: 0.60 to 0.89)] as was the incidence of any hypoglycemic event at any time of the day (over a 24 hour period) [U300: 71.5%; Lantus®: 79.3%; RR 0.90 (95% CI: 0.84 to 0.97)]. This result was also obtained across the entire 6-month study period, including the first 8 weeks of the trial.

There were similar findings between groups for adverse events, including injection site reactions and hypersensitivity reactions.

"*Reducing the risk of hypoglycemic events is imperative for effective management of diabetes, and EDITION II suggests that U300 reduces the risk of these events, even in a challenging patient population who have been on high basal insulin doses and oral medications without being able to achieve their treatment targets.*" said Hannele Yki-Järvinen, Professor of Medicine, University of Helsinki, Finland.

The EDITION II abstract is titled: **An investigational new insulin U300: glucose control and hypoglycemia in people with type 2 diabetes on basal insulin and OADs (EDITION II) (Yki-Järvinen et al. Oral presentation, 3rd December 2013 10:45 − 12:45 [ABS OP-0075]).**

EDITION III top-line results (study in insulin-naïve people with type 2 diabetes)

EDITION III compared U300 with Lantus® in 878 people with type 2 diabetes not previously treated with insulin and uncontrolled on oral medication. The primary endpoint of similar blood sugar level control (measured by HbA1c) from baseline to month 6 was met (-1.42% [95% CI: -1.511 to -1.326] in the U300 group, and -1.46% [95% CI: -1.555 to -1.367] in the Lantus® group).

Consistent with the results of the EDITION I and II studies, the rates of severe or nocturnal confirmed hypoglycemia in EDITION III from month 3 to 6 (main secondary endpoint) were lower with U300 (15.5% for U300 vs. 17.4% for Lantus®), but unlike EDITION I and II, the reduction was not statistically significant. Overall incidence of any documented hypoglycemia during the entire 6-month treatment period was numerically lower in the U300 group than in the Lantus® group (49.9% vs. 55.3%; no statistical analysis was performed.)

EDITION IV and EDITION JP I top-line results (studies in people with type 1 diabetes)

EDITION IV and JP1 studies compared U300 with Lantus® in people with type 1 diabetes treated with basal and mealtime insulin. EDITION IV enrolled 549 patients internationally, while EDITION JP I was conducted in 243 Japanese patients. The primary endpoint was met in both studies which showed similar reductions in HbA1c from baseline between U300 and Lantus® at 6 months. (EDITION IV: -0.40% [95% CI: -0.501 to -0.299] in the U300 group, and -0.44% [95% CI: -0.543 to -0.344] in the Lantus® group); EDITION JP I: -0.30% [95% CI: -0.411 to -0.183] in the U300 group, and -0.43% [95% CI: -0.542 to -0.313] in the Lantus® group).

In EDITION IV and EDITION JP I, confirmed and severe nocturnal hypoglycemia from month 3 to 6 was not pre-specified as a main secondary endpoint per study protocol. Analyses of several hypoglycemia categories are underway and will be presented, together with the EDITION III full results, at medical congresses in the first half of 2014.

In all of the studies, no differences in other adverse events were observed between U300 and Lantus®.

Sanofi anticipates the regulatory submissions to U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in the first half of 2014.

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 insulin + mealtime insulin) results have already been released.[1] The full EDITION II (basal insulin + oral therapy) results were presented at WDC 2013. Full results from

EDITION III, EDITION IV, EDITION JP I, and EDITION JP II (Japanese type 2 diabetes patients treated with basal insulin + oral therapy) will be presented at scientific meetings in 2014.

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. U300 has unique pharmacokinetic and pharmacodynamic profiles with studies demonstrating it has even flatter and more prolonged profiles than Lantus®.[2-5] U300 also offers the benefit of a smaller volume of subcutaneous injection compared with Lantus®.

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. Riddle M, et al. New insulin glargine formulation: glucose control and hypoglycaemia in people with type 2 diabetes using basal and mealtime insulin (EDITION I). *Diabetologia*. 2013;56 (Suppl 1):A220.
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.
3. Tillner J, et al. Euglycaemic single dose clamp profile of new insulin glargine formulation in subjects with type 1 diabetes is flat and prolonged. *Diabetologia.* 2013;56 (Suppl 1):A1033.
4. Jax T, et al. New insulin glargine formulation has a flat and prolonged steady state profile in subjects with type 1 diabetes. *Diabetologia.* 2013;56 (Suppl 1):A1029.
5. Shiramoto M, et al. Single dose of new insulin glargine Gla-300 formulation has a flatter and prolonged PK/PD profile than Gla-100 in Japanese subjects with type 1 diabetes. *Diabetologia.* 2013;56 (Suppl 1):A1031.

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.

Contacts:

Media Relations
Jack Cox
Tel.: + (33) 1 53 77 45 02
jack.cox@sanofi.com

Investor Relations
Sébastien Martel
Tel.: + (33) 1 53 77 45 45
ir@sanofi.com

Global Diabetes Communications
Tilmann Kiessling
Mobile: +49 17 26 15 92 91
Tilmann.kiessling@sanofi.com

U.S. Diabetes Communications
Susan Brooks
Office: +1 (0) 908 981 6566
Mobile: +1 (0) 201 572 49 94
susan.brooks@sanofi.com