



Sanofi Reports Positive Phase 3 Results for Toujeo[®] (insulin glargine [rDNA origin] injection, 300 U/mL)

– Meta-analysis of three late-stage trials in people with type 2 diabetes shows decreases in risk of low blood sugar events of up to 31% at night-time compared with Lantus[®] –

– All studies in the phase 3 “EDITION” clinical trial program, including a study with type 1 patients, met their primary endpoint –

– Toujeo dossier accepted by the EMA –

Paris, France – June 14 2014 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that, in a pooled analysis, investigational therapy Toujeo[®] (insulin glargine [rDNA origin] injection, 300 U/mL) consistently showed significantly fewer low blood sugar events (hypoglycemia) at any time of day, including night-time events, compared with Lantus[®] (insulin glargine [rDNA origin] injection, 100 U/mL). The pooled analysis comprised data from three differing type 2 patient populations. In this analysis, more pronounced, significant reductions in low blood sugar rates at any time of day, including nighttime, were observed with Toujeo during the 8-week titration period when compared with Lantus.

“Toujeo has been recently accepted for review by EMA and this important milestone is another step forward in expanding our insulin portfolio,” said Pierre Chancel, Senior VP, Global Diabetes Division, Sanofi. *“We continue to be encouraged by the positive Phase 3 results from EDITION, which demonstrated the potential of Toujeo to help meet unmet needs of people living with diabetes.”*

Type 2 Diabetes

The pooled analysis was comprised of studies I, II and III from the EDITION program, a worldwide and extensive series of Phase 3 studies evaluating the efficacy and safety of Toujeo in broader and diverse populations of people with type 2 diabetes. Full EDITION I and II results have been previously reported.

Full results from the EDITION III trial showed that significantly fewer people with type 2 diabetes, new to insulin therapy, experienced low blood sugar events during the night over the study period (post-hoc analysis) when treated with Toujeo compared with Lantus. This effect was numerically more pronounced, although not significant, during the first 8-week titration phase.

All of studies from the phase 3 EDITION clinical program presented at the 74th Scientific Sessions of the American Diabetes Association, like previously reported studies, met their primary endpoint by demonstrating similar blood sugar control with Toujeo as compared with Lantus.

Geremia Bolli, Principal Investigator of the EDITION III study and Professor of Endocrinology, University of Perugia, Italy, commented: *“Low blood sugar events, at any time of the day or night, should not be underestimated – particularly for those who are starting out with a new or alternate insulin therapy. As it is well known in clinical practice, many people go through a sensitive phase when starting insulin, and they tend to drop the treatment or not properly up-titrate when exposed to low blood sugar events. Reducing low blood sugar events in this particular phase is relevant in helping patients better manage diabetes.”*



EDITION I/II/III Meta-Analysis

In a diverse population of people with type 2 diabetes (n=2476), a post-hoc pooled analysis of EDITION I, II and III demonstrated the rate ratio (per participant-year) of night-time low blood sugar events was reduced by 31% (significant) for Toujeo compared with Lantus over the 6-month study period (rate ratio: 0.69 [95% CI: 0.57 to 0.84]; p=0.0002). In addition, the rate ratio was reduced (per participant-year) by 14% (significant) for low blood sugar events at any time of the day for Toujeo vs. Lantus (RR: 0.86 [95% CI: 0.77 to 0.97]; p=0.0116).

The EDITION I/II/III meta-analysis abstract is titled: **New Insulin Glargine 300 U/mL: Glycemic Control and Hypoglycemia in a Meta-analysis of Phase 3a EDITION Clinical Trials in People with T2DM. (Ritzel et al. Poster presentation, June 15, 2014 12:00 – 14:00 pm PDT [ABS 90-LB]).**

EDITION III Full Results

In people with type 2 diabetes who failed to control their blood sugar levels by treatments other than insulin, EDITION III (n=878) met its primary endpoint by showing similar blood sugar level control (reduction in HbA_{1c}) from baseline between Toujeo and Lantus at 6 months [LS mean change -1.42 (0.05) and -1.46 (0.05) respectively; difference 0.04% (95% CI: -0.09 to 0.17)].

The percentage of participants with severe or confirmed (defined by plasma glucose \leq 70 mg/dL) night-time low blood sugar events (nocturnal hypoglycemia) from week 9 to month 6 (pre-specified main secondary endpoint) was similar. Over the 6-month treatment period, the incidence of any night-time low blood sugar events (% of participants with \geq 1 event) was lower with Toujeo vs. Lantus [RR: 0.76 (95% CI: 0.59 to 0.99)], particularly in the insulin titration phase, with 26% risk reduction in patients experiencing night-time low blood sugar events with Toujeo vs. Lantus [RR: 0.74 (95% CI: 0.48 to 1.13)] during the first 8 weeks of treatment.

In addition, there was a 25% risk reduction (event/ participant-year) of low blood sugar events at any time of day or night across the entire 6-month study period for Toujeo vs. Lantus [RR: 0.75 (95% CI: 0.57 to 0.99)]. There were similar findings between groups for adverse events, including hypersensitivity reactions (6.9% vs. 5.7%, respectively) and injection site reactions (3.9% vs. 4.8%, respectively).

The EDITION III abstract is titled: **New Insulin Glargine 300 U/mL: Glycemic Control and Hypoglycemia in Insulin Naïve People with T2DM (EDITION 3). (Bolli et al. Oral presentation, June 14, 2014 09:00 am PDT [ABS 68-OR]).**

Toujeo Dosing Variation Study

Three-month sub-studies of EDITION I and II in type 2 diabetes patients showed varying the timing of Toujeo injections by \pm 3 hours at least two times each week resulted in similar blood glucose reduction and similar percentage of patients experiencing low blood sugar events compared with a fixed daily injection schedule.

The Toujeo -treatment groups of the original studies were further randomized to either a fixed dosing time (the same time in the evening) or an adaptable dosing regimen, which allowed 24 ± 3 hours between each dose of Toujeo on at least 2 days each week. This sub-study showed that the HbA_{1c} change (primary endpoint) was similar between regimens [EDITION I: difference 0.05% (95% CI: -0.19 to 0.30); EDITION II: difference 0.13% (95% CI: -0.15 to 0.42)]. Percentages of participants with \geq 1 low blood sugar event at any time of the day, or night, were also similar (EDITION I: 66.0% vs. 57.1% and EDITION II: 41.9% vs. 36.4%, for fixed vs. adaptable dosing time, respectively).



The Toujeo dosing variation study abstract is titled: **New Insulin Glargine 300 U/mL: Efficacy and Safety of Adaptable vs Fixed Dosing Intervals in People with T2DM. (Riddle MC et al. Poster presentation, June 14, 2014 11:30 am –13:30 pm PDT [ABS 919-P])**

Type 1 Diabetes: EDITION IV Results

EDITION IV full results showed that people with type 1 diabetes, randomized to Toujeo, experienced similar night-time and any-time of the day low blood sugar event rates with Toujeo compared with Lantus. In the insulin initiation phase, which was the first 8 weeks of the study, night-time low blood sugar event rates were significantly lower with Toujeo, compared with Lantus. Furthermore, EDITION IV results demonstrated similar glucose lowering and adverse event results for Toujeo regardless of whether it was injected in the morning or in the evening in type 1 patients. Variability in dosing was also investigated in two new subgroup studies in EDITION I and EDITION II. These studies demonstrated that glucose lowering and adverse events were similar for Toujeo vs Lantus when patients were able to vary their dosing schedule by up to ± 3 hours.

In people with type 1 diabetes, EDITION IV (n=549) met its primary endpoint by showing Toujeo was non-inferior to Lantus for blood sugar control at 6 months [LS mean change in HbA_{1c} -0.40 (0.05) and -0.44 (0.05) respectively; difference 0.04% (95% CI: -0.10 to 0.19)]. In this study, participants were randomized 1:1:1:1 to once-daily Toujeo or Lantus, morning or evening, while continuing meal-time insulin.

Event rates of confirmed or severe low blood sugar at any time of day or night across the entire 6-month study was similar for the two groups. The study indicated a 31% relative risk reduction (significant; event/patient-year) in night-time low blood sugar events in the first 8 weeks for Toujeo vs. Lantus (7.8% vs. 11.2%, [RR: 0.69 (95% CI: 0.53 to 0.91)]). There were similar findings between groups for adverse events. Neither glycemic control nor low blood sugar events differed between morning and evening injection groups.

The EDITION IV abstract is titled: **Glycemic Control and Hypoglycemia with New Insulin Glargine 300U/mL in People with T1DM (EDITION 4). (P.D. Home et al. Poster presentation, June 15, 2014 12:00 – 14:00 pm PDT [ABS 80-LB]).**

Toujeo[®] is the intended trade name for insulin glargine [rDNA origin] injection, 300 U/mL; formerly abbreviated as “U300”. U300 is not currently approved or licensed anywhere in the world.

On May 27, 2014, the European Medicines Agency (EMA) accepted Sanofi’s marketing authorization dossier for insulin glargine (rDNA origin) injection 300 U/mL, for EU countries.

Sanofi has submitted the New Drug Application (NDA) for insulin glargine [rDNA origin] injection, 300 U/mL to the U.S. Food and Drug Administration (FDA). The formal acceptance of the submission is pending.

Conference Call on Diabetes for the financial community



Sanofi will host a Thematic Conference Call on Diabetes for the financial community in connection with the upcoming American Diabetes Association's Scientific Sessions.

The call/webcast will take place on Monday, June 16, 2014 at:

6 pm Paris (CEST) | 5 pm London (BST) | 12 pm New York (EDT) | 9 am San Francisco (PDT)

The conference call will include a presentation followed by a Q&A session. It will be accessible through audio webcast at www.sanofi.com and via the following telephone numbers:

CALL IN NUMBERS	France	+33 (0) 1 70 77 09 44
	UK	+44 (0) 203 367 9453
	USA	+1 866 907 59 28

AUDIO REPLAY

An audio replay of the call will be available through the numbers below. The replay will be available approximately 2 hours after the end of the call

REPLAY NUMBERS	France	+33 (0) 1 72 00 15 00
	UK	+44 (0) 203 367 9460
	USA	+1 877 64 230 18

REPLAY ACCESS CODE	287626#
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About Sanofi

Sanofi, a 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).

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, 2013. 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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