



## Sanofi Announces Positive Results for Toujeo<sup>®</sup> in Phase III Study Extension in Japanese People with Uncontrolled Diabetes

*- Toujeo maintained similar blood sugar control vs. Lantus with fewer  
night-time low blood sugar events over 12-month study period -*

**Paris, France - June 6, 2015** - [Sanofi](#) announced today results from the EDITION JP 1 and EDITION JP 2 extension studies where Japanese participants (with type 1 and type 2 diabetes, respectively) received Toujeo<sup>®</sup> (insulin glargine [rDNA origin] injection, 300 U/mL) or Lantus<sup>®</sup> (insulin glargine [rDNA origin] injection, 100 U/mL) treatment for a total of 12 months. Over this entire study period, Toujeo maintained similar blood sugar control, with fewer people experiencing night-time low blood sugar events (blood sugar levels  $\leq$  54 mg/dL in the study with people with type 1 diabetes, and  $\leq$  70 mg/dL in the study with people with type 2 people), compared with Lantus. These new results from EDITION JP 1 and 2 were presented at the 75<sup>th</sup> Scientific Sessions of the American Diabetes Association.<sup>1,2</sup>

*“The results of the EDITION JP 1 and 2 extension studies reaffirm the clinical benefit that Toujeo can bring to people who are living with uncontrolled diabetes”,* said Pierre Chancel, Senior Vice President, Head of Global Diabetes, Sanofi. *“As a new addition to our portfolio, Toujeo gives patients a further option to help them reach their glycemic goals, and demonstrates our commitment to providing innovative therapies to enhance diabetes care.”*

In Japanese people with uncontrolled type 1 diabetes (EDITION JP 1), confirmed night-time low blood sugar ( $\leq$ 70 mg/dL) event rates and percentage of participants experiencing  $\geq$ 1 event over the 12-month study period were comparable in both groups. However, hypoglycemic event rate at the lower threshold ( $<$ 54 mg/dL) was 38% lower with Toujeo. Risk reduction of night-time low blood sugar events at this threshold showed that 21% fewer patients experienced night-time low blood sugar events with Toujeo vs. Lantus.

In Japanese people with type 2 diabetes uncontrolled on basal insulin and oral anti-diabetics (EDITION JP 2), incidence of low blood sugar events at night-time (blood sugar levels  $\leq$  70 mg/dL) was also reduced (27% fewer patients experiencing  $\geq$ 1 event over 12-month study period). Event rates (per patient-year) of low blood sugar at night-time and any time of the day (over 24 hours) were consistently lower with Toujeo compared with Lantus. Over the 12-month period, people with type 2 diabetes treated with Toujeo and oral medications also saw a slight reduction in body weight, in comparison to those treated with Lantus who saw a slight increase.

*“The additional data from the EDITION JP 2 study demonstrate Toujeo’s ability to achieve sustainable glycemic control in the Japanese type 2 population,”* commented Yasuo Terauchi, Principal Investigator of the EDITION JP 2 study and Professor at Yokohama City University School of Medicine, Kanagawa. *“The reduction in episodes of hypoglycemia observed and the additional weight findings demonstrated in EDITION JP 2 mean that Toujeo has the potential to help the people with type 2 diabetes in Japan to start and remain on insulin therapy in order to reach their long-term targets.”*



The abstracts are titled:

- **Sustained Glycemic Control and Less Nocturnal Hypoglycemia with New Insulin Glargine 300 U/mL compared with Glargine 100 U/mL over 12 Month in Japanese People with T1DM I (EDITION JP 1).** (Matsuhisa M et al. Presentation 987-P, June 6, 2015).
- **New Insulin Glargine 300 U/mL Provides Sustained Glycemic Control and Reduced Hypoglycemia over 12 Months Compared with Glargine 100 U/mL in Japanese People with T2DM Managed with Basal Insulin plus OAD(s) (EDITION JP 2).** (Terauchi Y et al. Presentation 98-OR, June 6, 2015).

### **EDITION JP 1 Full Results with 6 Month Extension<sup>1</sup>**

In EDITION JP 1 (n=228), Japanese people with type 1 diabetes that continued to receive treatment for an additional 6 months showed comparable blood sugar level control (reduction in HbA<sub>1c</sub> and FPG) from baseline between Toujeo and Lantus at 12 months (mean [SD] change -0.20 [0.80] % and -14.0 [86.5] mg/dL and (mean [SD] change -0.25 [0.72] % and -7.0 [93.2] mg/dL respectively).

The percentages of participants with  $\geq 1$  severe or confirmed (defined as plasma glucose  $\leq 70$  mg/dL) night-time low blood sugar event over the 12-month study period were comparable between groups. At the lower  $< 54$  mg/dL threshold, a reduction in event rate was observed with Toujeo compared with Lantus during the night (rate ratio 0.62; 95% CI: 0.39 to 0.97). The percentage of participants experiencing  $\geq 1$  nocturnal event at this threshold was also reduced with Toujeo compared with Lantus (relative risk 0.79; 95% CI: 0.64 to 0.98). Severe hypoglycemia occurred in 12 and 11 participants receiving Toujeo and Lantus respectively. There were similar findings between groups for adverse events.

### **EDITION JP 2 Full Results with 6 Month Extension<sup>2</sup>**

In EDITION JP 2 (n=222), Japanese people with type 2 diabetes who failed to control their blood sugar levels on previous basal insulin and oral medication, and continued to receive treatment for an additional 6 months, showed similar blood sugar level control (reduction in HbA<sub>1c</sub> and FPG) from baseline between Toujeo and Lantus at 12 months (mean [SD] change -0.28 [0.84] % and -12.1 [56.6] mg/dL, and mean [SD] change -0.33 [0.79] % and -18.6 [43.3] mg/dL respectively).

The percentage of participants with  $\geq 1$  severe or confirmed (defined as plasma glucose  $\leq 70$  mg/dL) low blood sugar event at night-time over the 12-month treatment period was lower with Toujeo vs. Lantus (relative risk 0.73; 95% CI: 0.55 to 0.97). There were also consistently fewer nocturnal and at any-time (24 hours) confirmed ( $\leq 70$  mg/dL) or severe hypoglycemic events per patient-year seen with Toujeo compared with Lantus (rate ratio 0.41; 95% CI: 0.18 to 0.92; rate ratio 0.64; 95% CI: 0.44 to 0.94, respectively). Severe hypoglycemia was rare with only 3 and 2 events reported for Toujeo and Lantus respectively.

In addition, the patients treated with Toujeo lost some weight, compared with a slight increase in the Lantus group (-0.7 kg vs. 0.5 kg respectively; NS). There were similar findings between groups for adverse events.

### **About Toujeo**

Despite basal insulin being a cornerstone treatment for diabetes for decades, significant unmet medical needs remain a reality, with approximately half of patients on treatment not reaching their blood sugar level targets.<sup>3-8</sup> In addition, optimal insulin dose is often not reached during initiation or maintenance phase. Toujeo is a next-generation, once-daily basal insulin based on a broadly-used molecule (insulin glargine) with a well-established benefit-risk profile.<sup>9</sup> Its compact subcutaneous depot leads to more stable and more prolonged pharmacokinetic/pharmacodynamic (PK/PD) profiles.<sup>10-12</sup> Toujeo has been approved by the U.S. Food and Drug Administration (FDA), the



European Commission and Health Canada, and is under review by other regulatory authorities around the world.

## About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: [SAN](#)) and in New York (NYSE: [SNY](#)).

## References

1. Matsuhisa M et al. Sustained Glycemic Control and Less Nocturnal Hypoglycemia with New Insulin Glargine 300 U/mL compared with Glargine 100 U/mL over 12 Month in Japanese People with T1DM I (EDITION JP 1). Poster presentation 987-P at the American Diabetes Association 75<sup>th</sup> Scientific Sessions, Boston, MA, U.S. June 6, 2015.
2. Terauchi Y et al. New Insulin Glargine 300 U/mL Provides Sustained Glycemic Control and Reduced Hypoglycemia over 12 Months Compared with Glargine 100 U/mL in Japanese People with T2DM Managed with Basal Insulin plus OAD(s) (EDITION JP 2). Oral presentation 98-OR at the American Diabetes Association 75<sup>th</sup> Scientific Sessions, Boston, MA, U.S. June 6, 2015.
3. Banegas JR, López-García E, Dallongeville J, et al. Eur Heart J. 2011;32(17):2143-52, DOI: 10.1093/eurheartj/ehr080.
4. Stark Casagrande S, Fradkin JE, Saydah SH, et al. Diabetes Care. 2013;36(8):2271-9, DOI: 10.2337/dc12-2258.
5. Chan JCN, Gagliardino JJ, Baik SH, et al. Diabetes Care. 2009;32(2):227-33, DOI: 10.2337/dc08-0435.
6. Choi YJ, Kim HC, Kim HM, et al. Diabetes Care. 2009;32(11):2016-20, DOI: 10.2337/dc08-2228.
7. Steinberg BA, Bhatt DL, Mehta S, et al. American Heart Journal. 2008;156(4):719-27, DOI: 10.1016/j.ahj.2008.05.020.
8. Vouri SM, Shaw RF, Waterbury NV, et al. Journal of managed care pharmacy : JMCP. 2011;17(4):304-12, DOI, <http://www.ncbi.nlm.nih.gov/pubmed/21534641>
9. Gerstein HC, Bosch J, Dagenais GR, et al. The New England journal of medicine. 2012;367(4):319-28, DOI: 10.1056/NEJMoa1203858.
10. Steintraesser A, Schmidt R, Bergmann K, et al. Diabetes, Obesity and Metabolism. 2014;16(9):873-6, DOI: 10.1111/dom.12283.
11. Becker RHA, Dahmen R, Bergmann K, et al. Diabetes Care. 2015;38(4):637-43, DOI: 10.2337/dc14-0006.
12. Shiramoto M, Eto T, Irie S, et al. Diabetes, Obesity and Metabolism. 2014: epub ahead of print, DOI: 10.1111/dom.12415.

## Sanofi 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 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, 2014. 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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## Contacts:

### Media Relations

Jack Cox  
Tel.: + (33) 1 53 77 46 46  
[mr@sanofi.com](mailto:mr@sanofi.com)

### Investor Relations

Sébastien Martel  
Tel.: + (33) 1 53 77 45 45  
[ir@sanofi.com](mailto:ir@sanofi.com)



**Global Diabetes Communications**

Tilmann Kiessling

Mobile: +(49) 17 26 15 92 91

[tilmann.kiessling@sanofi.com](mailto:tilmann.kiessling@sanofi.com)