



Sanofi to present new clinical data, including results from the investigational new insulin U300, at the American Diabetes Association 73rd Scientific Sessions

Paris, France - June 18, 2013 – Sanofi (EURONEXT : SAN and NYSE : SNY) announced today that clinical data highlighting the company's ongoing commitment to advancing diabetes care will be presented at the American Diabetes Association (ADA) 73rd Scientific Sessions in Chicago, USA (June 21–25, 2013). In total, more than 60 abstracts representing new data sets on Sanofi diabetes drugs, investigational drugs or medical devices are part of the official scientific program.

"The American Diabetes Association annual meeting provides an important opportunity for Sanofi to share significant data with the medical community and to demonstrate our focus on advancing scientific thinking in the field of diabetes treatment," said Pierre Chancel, Senior Vice President, Global Diabetes at Sanofi. *"The data being presented further support the company's leadership in integrated diabetes care and delivering personalized solutions that directly target the needs of people living with this disease."*

Among the study findings being presented in poster and oral scientific sessions are the following (abstracts have been posted on the ADA website):

Investigational new insulin U300

The EDITION I study compared the efficacy and safety of investigational new insulin U300 vs. Lantus® (insulin glargine) in people with type 2 diabetes using basal plus mealtime insulin. The EDITION I study is part of a larger Phase III clinical program.

"New insulin glargine formulation: glucose control and hypoglycemia in people with type 2 diabetes using basal and mealtime insulin (EDITION I)"

Embargo lifts: Saturday, June 22, 10 am CST

Presenter: M. Riddle, Oregon Health and Science University, Portland, USA

Location: Poster Hall

The pharmacodynamic and pharmacokinetic properties of the investigational new insulin U300 were examined in a double-blind, randomized study in patients with type 1 diabetes:

"Euglycemic clamp profile of new insulin glargine U300 formulation in patients with type 1 diabetes (T1DM) is different from glargine U100"

Embargo lifts: Saturday, June 22, 10 am CST

Presenter: R. Dahmen, Sanofi, Frankfurt am Main, Germany

Location: Poster Hall (also available as an ePoster on the ADA website after 10 am, June 22)

"New insulin glargine U300 formulation evens and prolongs steady state PK and PD profiles during euglycemic clamp in patients with type 1 diabetes (T1DM)"

Embargo lifts: Saturday, June 22, 1:45 pm CST

Presenter: T. Jax, Profil, Neuss, Germany

Location: W-375A



Lyxumia® (lixisenatide)*

Lyxumia®, the first once-daily prandial GLP-1 receptor agonist, is approved in the European Union for the treatment of adults with type 2 diabetes mellitus to achieve glycemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycemic control.

Lyxumia® data include two analyses investigating its post-prandial mechanism of action:

"Once-daily lixisenatide as add-on to basal insulin ± OADs in patients with type 2 diabetes selectively reduces postprandial hyperglycemic daytime exposure"

Embargo lifts: Saturday, June 22, 10 am CST

Presenter: M. Riddle, Oregon Health and Science University, Portland, USA

Location: Poster Hall (also available as an ePoster on the ADA website after 10 am, June 22)

"Efficacy of lixisenatide in the GetGoal clinical trial program: pooled analysis of postprandial metabolic outcomes"

B. Ahrén, Lund University, Sweden. Abstract publication only.

Further data include analyses of the effects of Lyxumia® in combination with basal insulin on HbA_{1c}, weight gain and symptomatic hypoglycemia in patients with type 2 diabetes:

"Expanding the basal-plus regimen: basal insulin + lixisenatide is more likely to achieve the composite outcome of HbA_{1c} <7%, no documented symptomatic hypoglycemia and no weight gain compared with basal + prandial insulin"

Embargo lifts: Saturday, June 22, 10 am CST

Presenter: J. Rosenstock, Dallas Diabetes & Endocrine Center, Texas, USA

Location: Poster Hall (also available as an ePoster on the ADA website after 10 am, June 22)

"Meta-analysis of randomized controlled trials of lixisenatide as add-on to basal insulin in patients with type 2 diabetes mellitus"

Embargo lifts: Saturday, June 22, 10 am CST

Presenter: B. Charbonnel, University of Nantes, France

Location: Poster Hall (also available as an ePoster on the ADA website after 10 am, June 22)

ORIGIN (Outcome Reduction with Initial Glargine INtervention)¹

ORIGIN is a unique, seven-year landmark cardiovascular (CV) outcomes trial, evaluating Lantus® vs. standard care in over 12,500 individuals who are at high CV risk with pre-diabetes or early type 2 diabetes mellitus. Spanning 40 countries worldwide, it is the world's longest and largest randomized clinical trial of its type in this population, and the first to formally evaluate the effects of insulin on CV outcomes.

Results from a new sub-analysis of ORIGIN will be presented:

"Cancer outcomes in patients with dysglycemia on basal insulin: results of the ORIGIN trial"

Embargo lifts: Monday, June 24, 8 am CST

Presenter: L.J. Bordeleau, McMaster University, Ontario, Canada

Location: S-103B

ATLAS (Asian Treat to Target Lantus® Study)

The ATLAS study compared the effectiveness of a patient-led vs. physician-led initiation of Lantus® in 552 patients with type 2 diabetes in Asia and Russia. Due to the specific challenges faced by people living with diabetes in Asia, this study investigated whether self-adjustment of insulin in this population is similarly effective at lowering blood glucose levels as it is in Western diabetes patients.



Data from ATLAS includes:

"Asian Treat to Target Lantus Study (ATLAS): a 24 week randomized, multinational study"

Embargo lifts: Saturday, June 22, 10 am CST

Presenter: S. Garg, University of Colorado Health Sciences Center, Denver, Colorado, USA

Location: Poster Hall

"Evaluating the patient experience in the Asian Treat to Target Lantus Study (ATLAS): a 24-week randomized, multinational study"

Embargo lifts: Saturday, June 22, 10 am CST

Presenter: N. Freemantle, University College London, UK

Location: Poster Hall

BGStar®

Now available in 14 countries across four continents, our intuitive blood glucose monitoring (BGM) devices BGStar® and iBGStar® form a key part of our comprehensive patient-centric portfolio and are at the heart of our integrated approach to diabetes.

Key BGStar® data show that the performance of our self-monitoring BGM device achieves similar system accuracy as point of care testing systems for professional use:

"Evaluating system accuracy of blood glucose monitoring systems for point of care testing"

Embargo lifts: Saturday, June 22, 10 am CST

Presenter: G. Freckmann, Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Germany

Location: Poster Hall (also available as an ePoster on the ADA website after 10 am, June 22)

Sanofi will host a conference call for the financial community during the upcoming ADA 73rd Scientific Sessions. The call will include results from the ongoing EDITION Phase III program for the company's investigational new insulin U300 as well as a status update on the fixed-ratio combination of insulin glargine and lixisenatide.

The conference call will take place on Monday June 24, 2013, at 7 am CST (2 pm CET). Dial-in numbers and the audio webcast link will be accessible via www.sanofi.com

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.²

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).

Footnote

*Lixisenatide, a glucagon-like peptide-1 receptor agonist (GLP-1 RA), was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com, and is approved in Europe, Mexico and Australia for the treatment of patients with type 2 diabetes mellitus. Lyxumia is the proprietary name approved by the EMA, Australia and Mexico, and submitted to other health authorities for the GLP-1 RA lixisenatide. The proprietary name for lixisenatide in the United States is under consideration.

References

1. Gerstein H (ORIGIN Trial Investigators) et al. Basal Insulin and Cardiovascular and Other Outcomes in Dysglycemia. *New England Journal of Medicine* 2012; 367: 319–328.
2. International Diabetes Federation. *IDF Diabetes Atlas, 5th edition: 2012 update*. Brussels, Belgium, 2011. <http://www.idf.org/diabetesatlas> (Accessed: June, 2013)

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.

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