

# **EASD Abstracts Highlight Sanofi Commitment to Advancing Therapeutic Solutions in Diabetes Care**

- Findings to be presented from the ORIGIN trial plus clinical data on Lantus<sup>®</sup> (insulin glargine), Apidra<sup>®</sup> (insulin glulisine) and Lyxumia<sup>®</sup> (lixisenatide)\*, an investigational GLP-1 receptor agonist –

**Paris, France – September 26, 2012 -** Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that clinical data supporting its integrated portfolio of therapeutic solutions and demonstrating its ongoing commitment to advancing diabetes care will be presented at the European Association for the Study of Diabetes (EASD) 48<sup>th</sup> Annual Meeting in Berlin, Germany (October 1-5, 2012).

Highlights of the clinical data being presented are as follows (abstracts have been posted on the EASD website):

### ORIGIN (Outcome Reduction with Initial Glargine INtervention)<sup>1</sup>

ORIGIN is a landmark cardiovascular (CV) outcomes trial, evaluating Lantus® (insulin glargine) versus standard care in over 12,500 individuals who were at high CV risk with pre-diabetes or early type 2 diabetes. Spanning 40 countries worldwide, ORIGIN 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.

Primary ORIGIN data were presented earlier this year at the American Diabetes Association (ADA) Scientific Sessions 2012; further data/updates will be presented at the EASD Meeting, including:

#### "Unpublished results from the ORIGIN Trial"

When: Oral presentation, Friday 5 October, 8:30am – 9:30am CET

Presenter: M. Riddle, Oregon Health and Science University, Portland, U.S.A.

Location: Berlin Fair Exhibition Halls, Langerhans Hall

### Lantus<sup>®</sup> (insulin glargine)

Lantus<sup>®</sup> is a long-acting insulin indicated in the European Union to treat diabetes mellitus in adults, adolescents and children aged 2 years and above for the control of high blood sugar.

Key Lantus® data includes:

### "The International Study of Insulin and Cancer"

When: Oral presentation, Wednesday 3 October, 8:30am – 10:00am CET

Presenter: L. Abenhaim, LA-SER and LSH&TM, London, UK Location: Berlin Fair Exhibition Halls, Langerhans Hall



# "Improved glycemic control with once-daily insulin glargine in people with type 2 diabetes inadequately controlled on insulin detemir/OAD combination therapy (RESOLUTE)" [Abs 947-EASD]

When: Poster presentation 947, Thursday 4 October, 12:00pm – 1:00pm CET

Presenter: L. Lieverse, Maxima Medical Centre, Eindhoven, Netherlands

Location: Berlin Fair Exhibition Halls. Poster Hall

# "Relative contribution of basal and postprandial blood glucose to hyperglycemia in patients (Pts) with type 2 diabetes mellitus enrolled in the START study" [Abs 944-EASD]

When: Poster presentation 944, Thursday 4 October, 12:00pm – 1:00pm CET

Presenter: S. Harris, Western University, London, Canada

Location: Berlin Fair Exhibition Halls, Poster Hall

### Apidra<sup>®</sup> (insulin glulisine)

Apidra<sup>®</sup> is a rapid-acting insulin for adults with type 2 diabetes or adults and children (6 years and above in the EU) with type 1 diabetes to improve blood sugar control. Apidra<sup>®</sup> given by subcutaneous injection is usually used with a basal insulin.

Key Apidra® data includes:

# "Interim safety results from a European observational cohort study of children ages 6-12 with type 1 diabetes treated with insulin glulisine (OCAPI study)" [Abs 902-EASD]

When: Poster presentation 902, Thursday 4 October, 1:15pm – 2:15pm CET

Presenter: M. Konstantinova, University Pediatric Hospital, Sofia, Bulgaria

Location: Berlin Fair Exhibition Halls, Poster Hall

### Lyxumia® (lixisenatide)\*

Lixisenatide, a glucagon-like peptide-1 receptor agonist (GLP-1 RA), is in development for the treatment of patients with type 2 diabetes mellitus.

Key lixisenatide data includes:

## "Effects of lixisenatide once daily on gastric emptying and its relationship to postprandial glycaemia in type 2 diabetes mellitus" [Abs 808-EASD]

When: Poster presentation 808, Wednesday 3 October, 12:00pm – 1:00pm CET

Presenter: M. Lorenz, Sanofi Deutschland GmbH Location: Berlin Fair Exhibition Halls, Poster Hall

## "Efficacy and safety of once-daily lixisenatide in type 2 diabetes insufficiently controlled with basal insulin ± metformin: GetGoal-L study" [Abs 3-EASD]

When: Oral presentation 3, Tuesday 2 October, 11:15am – 11:30am CET

Presenter: R. Aronson, LMC Endocrinology Centres, Toronto, Canada

Location: Berlin Fair Exhibition Halls, Langerhans Hall

## "Once-daily lixisenatide added on to consistently titrated insulin glargine plus oral agents in type 2 diabetes: the GetGoal-Duo 1 study" [Abs 807-EASD]

When: Poster presentation 807, Wednesday 3 October, 12:00pm – 1:00pm CET

Presenter: J. Rosenstock, Dallas Diabetes and Endocrine Center at Medical City, Dallas, U.S.A.

Location: Berlin Fair Exhibition Halls, Poster Hall



To view additional materials related to Sanofi at the EASD, please click on <a href="http://www.epresspack.net/sanofi-at-easd/">http://www.epresspack.net/sanofi-at-easd/</a>

#### **About Diabetes**

Diabetes is a chronic disease that occurs in two main clinical presentations: 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). Nearly 35 million people worldwide are living with type 1 diabetes. And, the incidence of type 2 diabetes is growing at an alarming rate, with more than 310 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 innovative blood glucose monitoring systems. Sanofi markets both injectable and oral medications for people with type 1 or type 2 diabetes. Investigational compounds in the pipeline include an injectable GLP-1 agonist being studied as a single agent, in combination with basal insulin, and/or in combination with oral anti-diabetic agents.

### **About Sanofi**

Sanofi, a global and diversified 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 was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com. Lyxumia<sup>®</sup> is the proprietary name submitted to the EMA for the company's investigational GLP-1 RA lixisenatide. The proprietary name for lixisenatide in the United States is under consideration. Lixisenatide is not currently approved or licensed anywhere in the world.

#### Reference

1. ORIGIN Trial Investigators, Gerstein H, Yusuf S, et al. Basal Insulin and Cardiovascular and Other Outcomes in Dysglycemia. *N Engl J Med* 2012; 367:319-328

#### 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, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

### **Contacts**

Corporate Media Relations

Marisol Péron

Tel: +33 (0)1 53 77 45 02 Mobile: +33 (0)6 08 18 94 78 E-mail: Marisol.Peron@sanofi.com

Global Diabetes Division Communications

Cornelia Schaeffer Tel: +49 69 305 22353 Mobile: +49 173 68 960 57

E-mail: Cornelia.Schaeffer@sanofi.com

Investor Relations Sébastien Martel

Tel: +33 (0)1 53 77 45 45 E-mail: <u>ir@sanofi.com</u>