



Sanofi GetGoal Program on Lyxumia[®], as an Add-on to Basal Insulin, Shows Significant Positive Phase III Results

- Reduction in HbA1c without Significant Increase in Hypoglycemia -

Paris, France - May 31, 2011 - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that new results from a Phase III study showed that the investigational product Lyxumia[®] (lixisenatide), when used as an add-on therapy to basal insulin (in association with or without metformin), achieved its primary efficacy endpoint of significantly reducing HbA1c versus placebo for patients with type 2 diabetes without significantly increasing their risk of hypoglycemia.

GetGoal-L is one of nine studies in the GetGoal Phase III clinical program, and the second trial to investigate the benefits of lixisenatide 20µg once-daily combined with basal insulin. It was a randomized (double-blind), placebo-controlled study with a 24-week main treatment period, and a total of 495 patients received either lixisenatide or placebo.

GetGoal-L showed a significant reduction in HbA1c levels ($p=0.0002$) with lixisenatide, without a significant increase in the incidence of symptomatic hypoglycemia ($p=0.14$) versus placebo. In addition, patients treated with lixisenatide had significantly improved postprandial plasma glucose after a test meal ($p<0.0001$). Patients in the lixisenatide arm of the study also reported a significant reduction in body weight ($p<0.0001$). These results confirm those previously reported on GetGoal-L Asia, this time in a broader population including both Caucasian and Asian patients. As expected with a GLP-1, the most commonly reported adverse event with lixisenatide was nausea with a low rate of discontinuation.

"These positive efficacy and safety results are another important milestone in the GetGoal clinical trial program and show the potential value of adding Lyxumia[®] (lixisenatide) to basal insulin to improve glycemic control," said Pierre Chancel, Senior Vice President, Global Diabetes Division at Sanofi. *"The findings from this and previous studies reinforce a continuing positive trend demonstrating the potential of lixisenatide to improve the lives of people with type 2 diabetes."*

The full study results from GetGoal-L are planned to be presented at a medical congress.

About lixisenatide (AVE 0010)

Lixisenatide, a glucagon-like peptide-1 agonist (GLP-1), is in development for the treatment of patients with type 2 diabetes mellitus. Lixisenatide was in-licensed from Zealand Pharma A/S (Copenhagen, Denmark), www.zealandpharma.com. Lyxumia[®] is the intended trademark for lixisenatide. Lixisenatide is not currently approved or licensed anywhere in the world.

GLP-1 is a naturally-occurring peptide that is released within minutes of eating a meal. It is known to suppress glucagon secretion from pancreatic alpha cells and stimulate insulin secretion by pancreatic beta cells. GLP-1 receptor agonists are in development as an add-on treatment for type 2 diabetes, and their use is endorsed by the European Association for the Study of Diabetes, the American Diabetes Association, the American Association of Clinical Endocrinologists and the American College of Endocrinology.



About the GetGoal Phase III Clinical Program

The GetGoal Phase III clinical program will provide data for the efficacy and safety of lixisenatide in adults with type 2 diabetes treated with various oral anti-diabetic agents or insulin. With nine trials in the program, GetGoal started in May 2008 and has enrolled more than 4300 patients. To date GetGoal-X, GetGoal-Mono, GetGoal-L Asia and GetGoal-S have reported positive top-line results supporting efficacy and safety for lixisenatide. Further results are expected during 2011.

About the Sanofi Diabetes Division

Sanofi strives to help people manage the complex challenges of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insight that comes 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 association with basal insulins, 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, rare diseases, consumer healthcare, emerging markets and animal health. 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 labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products 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 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, 2010. 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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