News Releases

# Sanofi-aventis: Investigational Compound Once-Daily Lixisenatide Demonstrated Significant Improvement in Glucose Control in Patients With Type 2 Diabetes

- Phase III Study Results Also Demonstrated the Therapy had Acceptable Safety Profile

PARIS, Sept. 20 /CNW/ - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today the first Phase III results of the GetGoal clinical trial program assessing the efficacy and safety of lixisenatide, a once-daily GLP-1 receptor agonist, as monotherapy in patients with type 2 diabetes. These results were presented at the European Association for the Study of Diabetes (EASD) 46th Annual Meeting in Stockholm, Sweden.

"These results demonstrated lixisenatide as a once daily GLP-1 agent with substantial A1C reduction and a pronounced effect on post-meal glucose control," said Dr. John E. Gerich of the University of Rochester School of Medicine and an investigator of the presented study. "The pronounced effect on postprandial glucose control provides a rationale to investigate the combined effect of lixisenatide and long-acting insulins in patients with type 2 diabetes."

The safety and efficacy of lixisenatide as monotherapy in patients with type 2 diabetes was assessed in a 12-week, randomized, double-blind, multicenter Phase III study. The study found that lixisenatide monotherapy administered once daily significantly improved glycemic control with a pronounced postprandial effect. The study also demonstrated that the therapy had an acceptable safety profile in patients with type 2 diabetes.

A total of 361 patients with type 2 diabetes (baseline A1C levels: 7 to 10 percent, mean age 53.7 years, mean diabetes duration 2.5 years) not currently receiving glucose-lowering therapy were randomized to: lixisenatide two-step titration (10 microg for 1 week, 15 microg for 1 week then 20 microg; n=120); lixisenatide one-step titration (10 microg for 2 weeks then 20 microg; n=119) or placebo (n=122).

Lixisenatide significantly reduced A1C levels in both titration groups versus placebo (p less than 0.0001). There was a significantly higher number of patients achieving A1C levels less than or equal to 6.5 percent with lixisenatide (31.9% two-step, 25.4% one-step) and less than 7.0 percent (52.2% two-step, 46.5% one-step) versus placebo (p less than 0.01).

Lixisenatide significantly reduced the mean change from baseline two-hours postprandial glucose by respectively -4.51 and -5.47 mmol/L (p(less than)0.0001) in the one-step and two-step titration groups with mean decreases in body weight observed in all groups. In addition, lixisenatide once-daily reduced glucose excursion respectively by -3.77 and -4.36 mmol/L in the one-step and two-step titration groups with mean decreases in body weight observed in all groups.

Lixisenatide was well tolerated. Only one serious treatment-emergent adverse event (TEAE) occurred in the lixisenatide group (0.4%) versus five in the placebo group (4.1%). Nausea was the most frequent TEAE with lixisenatide (24.2% for lixisenatide 2-step, 20.2% for lixisenatide 1-step, 4.1% for placebo). The rate of symptomatic hypoglycemia was 1.7 percent and 1.6 percent in the lixisenatide and placebo groups, respectively.

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 by sanofi-aventis from Zealand Pharma A/S (Copenhagen, Denmark).

The efficacy and safety of lixisenatide once-daily is being assessed in the GetGoal Phase III clinical trial program. The GetGoal clinical trial program started in May 2008 and has enrolled more than 4,500 patients. The enrollment of the eight other studies of the GetGoal Phase III program assessing efficacy and safety of lixisenatide in adult patients with type 2 diabetes mellitus treated with various oral antidiabetic agents or insulin was completed at the end of 2009.

The next results of the GetGoal Phase III program are expected to be released in Q2 2011.

About GLP-1 Receptor Agonists

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 EASD, the American Diabetes Association, the American Association of Clinical Endocrinologists and the

American College of Endocrinology.

About the sanofi-aventis Diabetes Division

Sanofi-aventis strives to be a 360 degree partner delivering innovative and integrated solutions for people living with diabetes. The Company currently has insulin products that are also available as injection pens for people with type 1 or type 2 diabetes. Following the formation of its Diabetes Division, sanofi-aventis has agreements with other companies for the development of blood glucose monitoring solutions and the potential first regenerative treatment for diabetes. Investigational compounds also in the pipeline include the once-daily injectable GLP-1 agonist lixisenatide as monotherapy and in combination with basal insulin as well as long-acting insulin analogs.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). For more information, please visit: http://www.sanofi-aventis.com.

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