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Phase III of GetGoal Trial: Results Released

Sanofi-aventis 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 µg for 1 week, 15 µg for 1 week then 20 µg; n=120); lixisenatide one-step titration (10 µg for 2 weeks then 20 µg; n=119) or placebo (n=122).

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

Lixisenatide significantly reduced the mean change from baseline two-hours postprandial glucose by respectively -4.51 and -5.47 mmol/L ($p<0.0001$) 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.

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