Victoza® (liraglutide) provides significantly greater HbA1c reduction than lixisenatide in new clinical trial

Stockholm, Sweden, 16 September 2015 – Findings from a head-to-head trial comparing Victoza® (liraglutide) and lixisenatide, both in combination with metformin, demonstrated a significantly greater reduction in HbA1c of -1.83% for liraglutide vs -1.21% for lixisenatide in adults with type 2 diabetes. Results from the LIRA-LIXI trial were announced today in an oral presentation at the 51st Annual Meeting of the European Association for the Study of Diabetes (EASD) in Stockholm, Sweden.

The 26-week LIRA-LIXI trial compared the efficacy and safety of Victoza® versus lixisenatide, both as add-on to metformin in 404 people with type 2 diabetes. People with type 2 diabetes treated with Victoza® achieved a significantly greater reduction in HbA1c versus lixisenatide at 26 weeks, meeting the trial’s primary endpoint (-1.83% vs -1.21%; estimated treatment difference [ETD] -0.62% [-0.80; -0.44]; P<0.0001). In addition, more people treated with Victoza® achieved HbA1c targets of <7% (74.2% vs 45.5%; odds ratio (OR) 4.16; [2.58; 6.73]; P<0.0001) and ≤6.5% (54.6% vs 26.2%; OR 3.66; [2.31; 5.81]; P<0.0001) compared with lixisenatide.

“The significant difference in blood glucose control between liraglutide and lixisenatide reported in the LIRA-LIXI trial reinforces the value of liraglutide as an efficacious treatment for those with type 2 diabetes otherwise treated with oral glucose-lowering drugs,” said Professor Michael A Nauck, director and diabetologist, Division of Diabetology, St. Josef Hospital, Ruhr-University Bochum, Germany and principal investigator of the LIRA-LIXI trial. “Many people living with type 2 diabetes remain uncontrolled and it is crucial for these patients to gain control of their blood glucose levels to help prevent further complications from this disease.”

Furthermore, Victoza® demonstrated significantly greater reductions in fasting plasma glucose (-2.85 mmol/L vs -1.70 mmol/L; ETD -1.15 mmol/L [95% CI -1.51; -0.80]; P<0.0001) and mean 9-point self-measured plasma glucose (-2.64 mmol/L vs. -1.89 mmol/L; ETD -0.75 mmol/L [95% CI -1.08; -0.42]; P<0.0001) compared with lixisenatide. Lixisenatide had a smaller postprandial increment for the meal following the injection compared to Victoza® (morning meal: -2.12 mmol/L vs -0.88 mmol/L; ETD 1.24 mmol/L; [0.69; 1.79]; P<0.0001 for those injecting lixisenatide in the morning; and evening meal: -1.88 mmol/L vs -0.53 mmol/L; ETD 1.36 mmol/L; [0.44; 2.27]; P=0.0039 for those injecting lixisenatide in the evening). There was no difference at the
other meals of the day, leading to similar overall postprandial glucose control across all meals for lixisenatide and Victoza®.¹

Weight loss was observed in both treatment groups (Victoza®: -4.26 kg vs lixisenatide: -3.67 kg; ETD -0.59 kg [-1.55; 0.38]; \( P=0.2347 \)).¹ Systolic and diastolic blood pressure decreased with both Victoza® and lixisenatide treatment (systolic blood pressure: -4.70 mmHg vs -3.49 mmHg; ETD -1.21 mmHg [-3.87; 1.45]; \( P=0.3722 \); diastolic blood pressure: -2.62 mmHg vs -2.69 mmHg; ETD 0.07 mmHg [-1.53; 1.67]; \( P=0.9318 \), respectively).¹

The safety profile in the LIRA-LIXI trial was similar between the two treatment groups. The most common adverse events were gastrointestinal, which included nausea and diarrhoea. No severe hypoglycaemic episodes were reported.¹

**About the LIRA-LIXI Trial**

The trial was a 26-week, parallel group, open-label trial involving 404 adults with type 2 diabetes randomised 1:1.¹ The trial participants were randomised to Victoza® 1.8 mg or lixisenatide 20 µg, both as add-on to metformin (at maximum tolerated dose, 1000−3000 mg daily).¹ Dose escalation and administration of Victoza® and lixisenatide were according to the approved label for both drugs at the time of the trial.¹ Victoza® was administered once-daily at any time of the day irrespective of meals. Lixisenatide was administered once-daily within an hour prior to the morning or evening meal.¹

**About Victoza®**

Victoza® (liraglutide) is a human glucagon-like peptide-1 (GLP-1) analogue with an amino acid sequence 97% similar to endogenous human GLP-1. Like natural GLP-1, Victoza® works by stimulating the beta-cells to release insulin and suppressing glucagon secretion from the alpha cells only when blood sugar levels are high. Due to this glucose-dependent mechanism of action, Victoza® is associated with a low rate of hypoglycaemia.² In addition, Victoza® reduces body weight and body fat mass through mechanisms involving reduced appetite and lowered energy intake.²

Victoza® was launched in the EU in 2009 and is commercially available in more than 80 countries with more than 3 million patient years of use in people with type 2 diabetes globally.² ³ In Europe, Victoza® is indicated for treatment of adults with type 2 diabetes to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.²

*Hypoglycaemia has primarily been observed when Victoza® is combined with a sulfonylurea or basal insulin.

**UPDATE:** This is an updated version of the original press release. In this version, clarifications have been added in the paragraph about reductions in fasting plasma glucose.
About Novo Nordisk

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