

Press Release

3 October 2012

New analysis shows Victoza® (liraglutide) is more effective when used early in the management of type 2 diabetes¹

Berlin, Germany - A new retrospective analysis shows that patients with a baseline HbA_{1c} <8.5%, a shorter duration of diabetes (<4.9 years) and previous treatment with a single antidiabetic medicine or diet modification were most likely to achieve HbA_{1c} <7% with no weight gain and no hypoglycaemia*, over 26 weeks of treatment with liraglutide 1.8 mg.¹ The study analysed data pooled from seven phase 3 clinical trials and was presented at the 48th annual meeting of the European Association for the Study of Diabetes (EASD) in Berlin, Germany.

"We know from clinical practice that liraglutide is highly effective at controlling blood sugar levels, with the added benefit of weight loss," said Dr. Vanita Aroda, Physician Investigator from MedStar Health Research Institute, Hyattsville, USA. "These new results show an increased likelihood of achieving target glycaemic control (HbA_{1c} <7%), with no weight gain and no hypoglycaemia, when liraglutide is used earlier in the management of type 2 diabetes."

This new study retrospectively analysed clinical trial data, which included 1,530 patients with type 2 diabetes, using recursive partitioning analyses to identify factors that predict greatest therapeutic benefit in response to treatment with

* Episodes requiring assistance or self-treated with plasma glucose (PG)<56 mg/dL [<3.1 mmol/L]

liraglutide. Responders in the study were defined as those patients achieving a composite endpoint of HbA_{1c}<7% with no weight gain and no hypoglycaemia[†] over 26 weeks.

Key findings from the study include¹:

- Overall 34% of individuals treated with liraglutide 1.8 mg achieved the prespecified composite endpoint in the retrospective analysis.
- More patients with HbA_{1c}<8.5% at the start of the study reached the composite endpoint, compared to patients with HbA_{1c}≥8.5%, 46% vs 19% responders, respectively (p<0.0001).
- More patients with HbA_{1c}<8.5% at the start of the study and who had previously received treatment with a single antidiabetic medicine or diet modification reached the composite endpoint, compared to those who had received combination therapy (56% vs 36% responders, respectively, p<0.0001).
- In another subgroup of female patients, more patients with HbA_{1c}<8.5% at the start of the study, previous treatment with a single antidiabetic medicine or diet modification and a shorter duration of diabetes (<4.9 years) reached the composite endpoint, compared to patients with a longer duration of diabetes (≥4.9 years), 74% vs 49% responders, respectively (p=0.013).

About Victoza[®]

Victoza[®] 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[‡]. The mechanism of blood sugar lowering also involves a delay in gastric emptying.²

Victoza[®] was approved on 30 June 2009 by the European Commission in all 27 European Union member states. In Europe, Victoza[®] is indicated for treatment of adults with type 2 diabetes mellitus to achieve glycaemic control, in

[†] Episodes requiring assistance or self-treated with plasma glucose (PG)<56 mg/dL [<3.1 mmol/L]

[‡] Hypoglycaemia has primarily been observed when Victoza is combined with a sulphonylurea.

combination with metformin and or sulphonylurea or metformin and thiazolidinedione. On 25 January 2010, Victoza[®] was approved in the US as an adjunct to diet and exercise to improve blood sugar control in adults with type 2 diabetes. Victoza[®] has been commercially launched in more than 50 countries globally. Since its launch in 2009, Victoza[®] has been prescribed to more than half a million patients.³

Victoza[®] Phase 3 clinical trial programme

As the first once-daily GLP-1 analogue for the treatment of type 2 diabetes, the safety and efficacy of Victoza[®] has been extensively investigated in studies involving more than 6,000⁴ people around the world. The six trials of the LEAD[™] (Liraglutide Effect and Action in Diabetes) clinical development programme compared Victoza[®] against a number of commonly used antidiabetic medicines from a wide range of classes: SU (glimepiride), TZD (rosiglitazone), insulin (glargine) and GLP-1 (exenatide BiD).² In addition to the LEAD trials, Victoza[®] has been shown to be superior in reducing HbA_{1c} and body weight to sitagliptin, a commonly used DPP-4 inhibitor, in a head-to-head clinical trial.²

Headquartered in Denmark, Novo Nordisk is a global healthcare company with 89 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. For more information, visit novonordisk.com.

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 2. Victoza® Summary of Product Characteristics (2012).
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 3. Internal Calculations based on IMS Midas Quantum data, May 2012
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