Victoza® lowered the progression of kidney damage in adults with type 2 diabetes at high CV risk

Munich, Germany, 15 September 2016 – Novo Nordisk today announced that the progression of kidney damage was significantly lower with Victoza® treatment vs placebo, as measured by urinary albumin creatinine ratio, both added to standard of care in 9,340 adults with type 2 diabetes at high cardiovascular (CV) risk. Similar significant results were observed between Victoza® and placebo across subgroups (with no, mild or moderate renal impairment).\(^1\) The results were presented today at the 52\(^{nd}\) Annual Meeting of the European Association for the Study of Diabetes (EASD) 2016.\(^1\)

New onset or worsening kidney disease was part of a pre-specified secondary endpoint in the landmark LEADER CV outcomes trial. The overall risk reduction of 22\% was primarily driven by the component of new onset of persistent macroalbuminuria (high levels of a protein called albumin found in the urine), which occurred significantly less (26\%) in adults treated with Victoza® vs placebo.\(^1\)

“Kidney disease is one of the more common long-term complications of type 2 diabetes, affecting up to 40\% of adults living with this disease,” said Dr Johannes Mann, LEADER investigator and Professor of Medicine, Dept. of Nephrology & Hypertension, University of Erlangen-Nuremberg, Germany. “These findings are clinically relevant as they indicate that Victoza® may have the potential to reduce the risk of kidney disease in adults with type 2 diabetes at high cardiovascular risk.”

Furthermore, a secondary analysis on hospitalisations for heart failure (HF) demonstrated that Victoza® did not increase the risk of hospitalisation for HF in adults with type 2 diabetes and a history of HF vs placebo. In a pre-specified secondary analysis for LEADER, Victoza® reduced hospitalisations for HF by 13\% vs placebo across all adults with or without a history of HF at baseline.\(^1\)

The proportion of adults experiencing adverse events was similar between the Victoza® and the placebo groups (62.3\% vs 60.8\% respectively). The most common adverse events leading to the discontinuation of Victoza® were gastrointestinal events. The incidence of pancreatitis was non-significantly lower in the Victoza® group than in the placebo group.\(^2\)
About LEADER

LEADER was a multicentre, international, randomised, double-blind, placebo-controlled trial investigating the long-term (3.5 – 5 years) effects of Victoza® (liraglutide up to 1.8 mg) compared to placebo, both in addition to standard of care, in people with type 2 diabetes at high risk of major cardiovascular events. Standard of care was comprised of lifestyle modifications, glucose-lowering treatments and cardiovascular medications.

LEADER was initiated in September 2010 and randomised 9,340 people with type 2 diabetes from 32 countries. The primary endpoint was the first occurrence of a composite cardiovascular outcome comprising cardiovascular death, non-fatal myocardial infarction (heart attack) or non-fatal stroke.

Over a median follow-up of 3.8 years, Victoza® significantly reduced the risk of the composite primary endpoint of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke by 13% vs placebo. There was a significant 22% reduction in cardiovascular death with Victoza® treatment vs placebo and non-significant reductions in non-fatal myocardial infarction and non-fatal stroke.

Kidney disease was assessed by the composite renal outcome, defined as: high levels of a protein called albumin found in the urine (new onset of persistent macroalbuminuria); kidney filtration function (persistent doubling of serum creatinine); need for dialysis (continuous renal replacement therapy); or death due to kidney disease.

About kidney disease and type 2 diabetes

Diabetes significantly increases the risk of developing diabetic nephropathy, which is the leading cause of end-stage kidney disease (or kidney failure). Diabetic nephropathy affects 30-40% of those with diabetes and males with type 2 diabetes have a six-fold increased risk of developing this condition compared to those without type 2 diabetes. Furthermore, the presence of diabetic nephropathy is known to be a significant risk factor for cardiovascular disease.

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.

Victoza® was approved in the EU in 2009 and is commercially available in more than 85 countries, treating more than 1 million people with type 2 diabetes globally. In Europe, Victoza® is indicated for the treatment of adults with type 2 diabetes to achieve glycaemic control as monotherapy, when metformin is considered inappropriate, and 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. In the US, Victoza® was approved in 2010 as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes.
Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,300 people in 75 countries and markets its products in more than 180 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

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References
1. Results of the liraglutide effect and action in diabetes - evaluation of cardiovascular outcome results (LEADER) trial. Scientific Sessions at the 52nd Annual Meeting of the European Association for the Study of Diabetes (EASD) 2016. 15 September 2016.