People with diabetes may achieve improved glycaemic control with Tresiba® versus glargine U100, without an increase in hypoglycaemia

Berlin, Germany, 2 October 2018 – According to results of a post-hoc analysis people with both type 1 and type 2 diabetes in clinical practice may achieve improved glycaemic control (HbA1c) with Tresiba® (insulin degludec) versus insulin glargine U100, without an increase in hypoglycaemia (potentially dangerous low blood sugar).\(^1\) The results of this new analysis from the SWITCH 1 and 2 trials were presented today at the 54th Annual Meeting of the European Association for the Study of Diabetes (EASD 2018) in Berlin, Germany.

Lowering blood sugar to target levels is important to help prevent the complications of diabetes, but reductions can increase the risk of hypoglycaemia. In this post-hoc analysis, based on the reduction in hypoglycaemia risk with Tresiba® found in the maintenance period of the SWITCH trials, it is estimated that people with diabetes may achieve a mean HbA1c reduction of 0.70% (type 1 diabetes) and 0.96% (type 2 diabetes) with Tresiba® compared to insulin glargine U100 at similar rates of hypoglycaemia.\(^1\)

“Episodes of hypoglycaemia can be dangerous for people with diabetes and can often be a significant barrier to achieving glycaemic control,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “These findings add to already published evidence showing a reduced risk of hypoglycaemia with Tresiba®, providing further confidence that this treatment may help people with diabetes achieve blood sugar control.”

This post-hoc analysis is based on patient-level data from the SWITCH 1 and 2 trials. The SWITCH trials demonstrated statistically significantly lower rates of overall symptomatic hypoglycaemia versus insulin glargine U100 in people with type 1 and type 2 diabetes.\(^2,3\)

About the new analysis
This post-hoc analysis investigated the individual patient-level risk of hypoglycaemia by HbA1c with Tresiba® and insulin glargine U100 to compare how glycaemic control differs at a similar rate of hypoglycaemia. For each trial participant at each visit their HbA1c level was linked with the number of hypoglycaemic events (blood glucose-confirmed [<3.1

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**Press Release**

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mmol/L] with symptoms or severe [third-party assistance]) since last visit. Reduction of hypoglycaemia risk with Tresiba® was calculated using the reduction in hypoglycaemia seen with Tresiba® compared to insulin glargine U100 in the SWITCH trials.¹

**About SWITCH 1 and 2**

SWITCH 1 and SWITCH 2 were two phase 3b, 64-week, double-blinded, randomised, treat-to-target, 2-period cross-over trials that investigated the hypoglycaemia profile of Tresiba® compared with insulin glargine U100 in people with type 1 and type 2 diabetes and at least one risk factor for hypoglycaemia, respectively. The trial design included a titration period in which the doses of study treatments (Tresiba® or insulin glargine U100) were gradually increased over a 16-week period, followed by a 16-week maintenance period during which a stable dose of study treatment was maintained.²,³ The primary endpoint was the number of severe or blood glucose-confirmed symptomatic hypoglycaemic episodes observed in participants during the maintenance period.²,³

**About hypoglycaemia**

Hypoglycaemia occurs when blood sugar levels are too low and cannot provide the body’s organs with the energy they need. Hypoglycaemia can cause a range of symptoms including confusion, trembling, sweating, increased heart rate, difficulty with concentration and speech.⁴,⁵ In severe cases it can lead to a seizure, coma or even death.⁴,⁶

**About Tresiba®**

Tresiba® (insulin degludec) is a once-daily basal insulin that provides a duration of action beyond 42 hours with a flat and stable glucose-lowering effect.⁷,⁸ Tresiba led to an effective reduction in HbA₁c in clinical trials and showed a lower risk of hypoglycaemia in certain patient populations and studies compared to insulin glargine U100, in particular in type 2 diabetes.²,³,⁶,⁹ It also provides for a lower day-to-day variability in glucose lowering effect versus insulin glargine U100.⁸ Tresiba® received its first regulatory approval in September 2012 and has since been approved in more than 80 countries globally. It is commercially available in more than 61 countries.

**About Novo Nordisk**

*Novo Nordisk is a global healthcare company with 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 43,100 people in 79 countries and markets its products in more than 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.*
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References