press release

Tresiba® and Victoza® receive positive opinions from CHMP for label updates expanding indications for use in adults with type 2 diabetes

Copenhagen, Denmark, 21 March 2014 - The Committee for Medicinal Products for Human Use (CHMP) issued positive opinions for expanded use of Tresiba® (insulin degludec) and Victoza® (liraglutide) in type 2 diabetes. Once the European Commission approves the label expansion, physicians will be able to prescribe Tresiba®, the once-daily, long-acting basal insulin in combination with GLP-1 receptor agonists, such as Victoza®. Similarly, Victoza®, the once-daily human glucagon-like peptide-1 (GLP-1 analogue), can be prescribed in combination with a basal insulin.

Tresiba® was approved in Europe in 2013 for once-daily use in adults with type 1 and type 2 diabetes as a monotherapy and in combination with oral anti-diabetic (OAD) medicinal products or with mealtime insulin[1]. Victoza® was approved in Europe in 2009 for the treatment of type 2 diabetes in adults in combination with OADs[2].

"This is excellent news for patients with type 2 diabetes and their physicians. The update expands the options physicians have to individualise therapy for their patients and help them achieve glycaemic targets, especially if they have concerns about hypoglycaemia and weight gain," said Professor Chantal Mathieu, Katholieke Universiteit Leuven, Belgium, the lead study investigator of the BEGIN™: VICTOZA® ADD-ON trial.

The CHMP recommendation for both Tresiba® and Victoza® was based on efficacy and tolerability data from four phase 3 clinical trials[3-6]. All four trials were conducted in adults with type 2 diabetes.

About the studies

Pivotal data came from the BEGIN™: VICTOZA® ADD-ON[3] 26-week open-label extension to a 104-week clinical trial in which 57% of patients treated with Tresiba® in combination with metformin achieved a target HbA_{1c} <7%. Patients who did not achieve the HbA_{1c} target were randomised to receive either a single dose of NovoRapid® (insulin aspart), with the largest meal or once-daily Victoza® in addition to Tresiba® and metformin for 26 weeks.

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Study results include:

- The addition of Victoza® once-daily versus a single dose of NovoRapid® showed statistically significantly greater reduction of HbA_{1c} (-0.73% versus -0.40%*) and body weight (-3.03 kg versus +0.72 kg*)[3].
- The observed rate of confirmed hypoglycaemic episodes (per patient year of exposure) was significantly lower when adding Victoza® once-daily compared to a single dose of NovoRapid® (1.0 versus 8.15; estimated rate ratio: 0.13; 95% CI 0.08 to 0.21; p<0.0001)[3].

The three supportive studies included in the CHMP review were:

- DUAL™ I, which compared the efficacy and safety of IDegLira (a combination of insulin degludec and liraglutide in one pen) versus Tresiba® or Victoza® alone in patients with type 2 diabetes, which was uncontrolled on metformin ± pioglitazone[4].
- DUAL™ II, which compared the efficacy and safety of IDegLira versus Tresiba® alone in people with type 2 diabetes, which was uncontrolled on basal insulin (20-40U) + metformin ± sulfonylurea or glinides[5].
- LIRA-DETEMIR™, which compared a combination of the basal insulin Levemir® (insulin detemir) and Victoza® versus Victoza® alone in insulin-naïve patients with type 2 diabetes on metformin[6].

About Tresiba®

Tresiba® (insulin degludec) is the global brand name for insulin degludec, a basal insulin discovered and developed by Novo Nordisk. Once-daily Tresiba® provides a long duration of action beyond 42 hours, allowing for flexibility in day-to-day dosing time when needed with a minimum of eight hours and a maximum of 40 hours between injections, without compromising efficacy or risk of hypoglycaemia. Tresiba® has been studied in a large-scale clinical trial programme, BEGIN™, examining its impact on glucose control, hypoglycaemia and flexibility in day-to-day dosing time when needed. Tresiba® has received regulatory approval in Argentina, Aruba, Bangladesh, Brazil, Chile, El Salvador, the EU, Iceland, India, Japan, Lebanon, Lichtenstein, Macedonia, Mexico, Norway, Russia and Switzerland.

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†. In addition, Victoza® reduces body weight and body fat mass through mechanisms involving reduced appetite and lowered food intake.

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*The numbers used for the label update were calculated using estimated means whereas the numbers used in the BEGIN™: VICTOZA® ADD ON trial publication were calculated using observed means.

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Victoza® was launched in the EU in 2009 and is commercially available in more than 65 countries globally. Currently, there are more than 790,000 patients receiving Victoza® worldwide[7]. In the US, Victoza® was approved on 25 January 2010 as an adjunct to diet and exercise to improve blood sugar control in adults with type 2 diabetes.

†Hypoglycaemia has primarily been observed when Victoza® is combined with a sulfonylurea.

Headquartered in Denmark, Novo Nordisk is a global healthcare company with 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Novo Nordisk employs approximately 38,000 employees in 75 countries, and markets its products in more than 180 countries. For more information, visit novonordisk.com.

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