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press release

Ryzodeg[®] provides successful glycaemic control with fewer injections than a basal-bolus regimen

Vienna, Austria, Thursday 18 September 2014 - Data presented today at the 50th Annual Meeting of the European Association for the Study of Diabetes (EASD) show that Ryzodeg[®] (insulin degludec/insulin aspart) administered twice daily, provides successful glycaemic control with fewer injections than a basal-bolus regimen^{1*}.

Ryzodeg[®] is a combination of two distinct insulin analogues (insulin degludec and insulin aspart in the ratio of 70% and 30%), making it the first combination of a basal insulin with an ultra-long duration of action and a well-established mealtime insulin in one pen for people with type 2 diabetes²⁻⁴.

"Patients currently using basal-bolus regimens may need to take up to four daily injections, which can be a great burden and very inconvenient. Ryzodeg[®] is a new treatment option which provides proven glycaemic control, with fewer injections and reduced rates of hypoglycaemia compared to basal-bolus regimens," said Dr Helena Rodbard, the study's principal investigator and endocrinologist in Rockville, MD, USA. "This new treatment offers the potential for a simple alternative to basal-bolus for patients who require intensification of basal insulin regimens," she added.

The study presented at EASD was a 26-week randomised multinational phase 3b trial, where patients previously treated with basal insulin were randomised to a regimen of either twice daily Ryzodeg[®], or a basal-bolus regimen of once-daily insulin degludec plus two to four injections of insulin aspart¹. The study did not meet its primary endpoint of non-inferiority; however, the results showed that HbA_{1c} was reduced for patients on either regimen, to 7.0% and 6.8% respectively, with no significant difference between the two regimens¹. Patients who received Ryzodeg[®] experienced a numerically lower rate of overall and nocturnal confirmed hypoglycaemic episodes¹, 19% and 20% less, respectively. They also gained significantly less weight ($p < 0.05$) over the course of the

*A basal-bolus routine involves taking a longer acting form of insulin to keep blood glucose levels stable through periods of fasting and separate injections of shorter acting insulin to prevent rises in blood glucose levels resulting from meals.

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study and used a significantly lower daily insulin dose¹ (12%; $p < 0.05$) versus the basal-bolus regimen.

Type 2 diabetes is a progressive disease⁵, which means some patients will need to intensify insulin treatment eventually by adding mealtime insulin – bolus therapy – to achieve or maintain their glycaemic targets over time⁵. Studies have shown that more than 50% of people with type 2 diabetes on basal insulin alone are not achieving their glycaemic targets as measured by HbA_{1c}⁶⁻⁸. Complications from diabetes caused by failing to keep optimal glycaemic control can be serious and may include problems such as heart disease, stroke, blindness, kidney disease, nerve damage and premature mortality^{9,10}.

About Ryzodeg®

Ryzodeg® is a combination of two distinct insulin analogues, insulin degludec and insulin aspart in the ratio of 70% and 30%. In a multinational trial, Ryzodeg® delivered twice daily at main meals offered a successful reduction in HbA_{1c}^{2,4} with lower risk of hypoglycaemia versus biphasic insulin aspart 30 in people with type 2 diabetes⁴. In other studies no apparent differences were shown between Ryzodeg® and its comparators, with respect to adverse events and standard safety parameters^{4,11-13}. Ryzodeg® has been approved in Aruba, Brazil, Chile, Costa Rica, El Salvador, the EU, Hong Kong, Iceland, India, Israel, Japan, Kazakhstan, Macedonia, Mexico, Norway, Russia, South Korea and Switzerland.

About the clinical trial programme

The clinical trial programmes for insulin degludec (BEGIN®) and Ryzodeg® (BOOST®) comprise the largest in the field of insulin therapy, with more than 11,000 people included. Novo Nordisk completed the phase 3a BOOST® programme in 2010. This programme consisted of six randomised, controlled, treat-to-target trials in more than 30 countries. More than 2,000 people were included in the development programme. The programme was designed after consultancy with regulatory agencies in Europe, Japan and USA.

About Novo Nordisk

Headquartered in Denmark, Novo Nordisk is a global healthcare company with more than 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 40,700 employees in 75 countries, and markets its products in more than 180 countries. For more information, visit novonordisk.com.

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