*Not intended for UK media*

***Diabetes Care* publishes phase 3a data demonstrating safety and efficacy of IDegLira in people with type 2 diabetes uncontrolled on basal insulin**

**Bagsværd, Denmark, 11 August 2014** –Today, *Diabetes Care* publishes phase 3a findings from the DUAL™ II trial investigating IDegLira, the once-daily combination of Tresiba® (insulin degludec) and Victoza® (liraglutide) in one pen for people with type 2 diabetes switching from basal insulin therapy. Data from the DUAL™ II trial demonstrated a statistically significant greater glucose-lowering effect with IDegLira than insulin degludec at equivalent insulin doses. Weight loss and a low rate of hypoglycaemia were comparable to insulin degludec.1

IDegLira demonstrated a mean HbA1c (blood glucose) reduction of 1.9% from baseline, versus 0.9% with insulin degludec at equivalent insulin doses (45 units). 60% of people treated with IDegLira achieved a HbA1c goal of ˂7.0% compared to 23% treated with insulin degludec. At the end of trial, 40% of the people who met HbA1c goal did so with no confirmed hypoglycaemic episodes and with no weight gain, compared to 8.5% of people treated with insulin degludec. People treated with IDegLira had a statistically significant mean weight loss of 2.7 kg from baseline compared to no change with insulin degludec at the end of the trial (p<0.0001).1

“IDegLira is a new innovative option for people with type 2 diabetes, who would otherwise have to consider more intensive insulin regimens accompanied by weight gain and increased risk of hypoglycaemic episodes,” said Tina Vilsbøll, Professor, MD, DMSc, Chief Consultant Endocrinologist and Head of Diabetes Research Division, Gentofte Hospital, University of Copenhagen, Denmark.

IDegLira demonstrated greater control over meal-related peaks in blood glucose levels and during periods of fasting than insulin degludec. Glucose concentrations before and after meals were significantly lower with IDegLira than insulin degludec resulting in a mean plasma glucose concentration of 7.5 mmol/L (135.1 mg/dL) versus 8.7 mmol/L (156.8 mg/dL) for insulin degludec ( p<0.0001). At 26 weeks, fasting plasma glucose (FPG) decreased by 3.5 mmol/L with IDegLira and by 2.6 mmol/L with insulin degludec, to 6.2 mmol/L and 7.0 mmol/L respectively (p=0.0019).1

There were no apparent differences between the treatment groups with respect to adverse events and standard safety parameters during the trial.1 None of the people treated with IDegLira, who had previously been on basal insulin, discontinued treatment due to nausea during the study period or due to ineffective therapy during the first 2 weeks of treatment.1

**About IDegLira (insulin degludec/liraglutide)**

IDegLira is a combination of insulin degludec (Tresiba®), a once-daily basal insulin analogue with an ultra-long duration of action, and liraglutide (Victoza®), the once-daily human GLP-1 analogue, which is being developed for the treatment of type 2 diabetes. In people with type 2 diabetes uncontrolled on basal insulin therapy, once-daily IDegLira has demonstrated a significant reduction in HbA1c of 1.9%, weight loss of 2.7 kg, and a low rate of hypoglycaemia comparable to insulin degludec. In clinical trials, IDegLira was administered once-daily independently of meals and has shown consistent HbA1c reductions in insulin-naïve people with type 2 diabetes. IDegLira is being investigated in the Phase 3 DUAL™ clinical trial programme. Novo Nordisk received positive opinion from the [Committee for Medicinal Products for Human Use](http://www.google.com/url?sa=t&rct=j&q=chmp&source=web&cd=1&cad=rja&uact=8&sqi=2&ved=0CBwQFjAA&url=http%3A%2F%2Fwww.ema.europa.eu%2Fema%2Findex.jsp%3Fcurl%3Dpages%2Fabout_us%2Fgeneral%2Fgeneral_content_000094.jsp&ei=IlvXU6_lJ9a3yAThhIH4Bw&usg=AFQjCNHIG9wwf1wxqpBDYv62tTBFcQ0TiQ) (CHMP) for IDegLira in the EU on 24 July 2014.

**About the DUAL™ II Trial**

DUAL™ II (398 people) – a 26-week, randomised, parallel, two-arm, double-blinded, multicentre, multinational trial conducted at 75 sites across 7 countries. The trial compared the efficacy and safety of IDegLira and insulin degludec once daily, both added on to metformin in adults with type 2 diabetes uncontrolled on basal insulin (20–40 units) in combination with 1–2 oral antidiabetic therapies (metformin ± sulfonylurea/glinides). Sulfonylureas and glinides were discontinued at randomisation. In this trial, the allowed maximum dose of insulin degludec in the treatment arms was 50 units so as to be able to demonstrate the contribution of the liraglutide component of IDegLira on glycaemic control. The top-line results were reported in 2012.

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 40,000 employees in 75 countries, and markets its products in more than 180 countries. For more information, visit novonordisk.com.

### Further information

|  |  |  |
| --- | --- | --- |
| *Media:* |  |  |
| Katrine Sperling | +45 4442 6718 | [krsp@novonordisk.com](mailto:krsp@novonordisk.com) |
| Ken Inchausti (US) | +1 609 514 8316 | [kiau@novonordisk.com](mailto:kiau@novonordisk.com) |
| *Investors:* |  |  |
| Kasper Roseeuw Poulsen | +45 3079 4303 | [krop@novonordisk.com](mailto:krop@novonordisk.com) |
| Jannick Lindegaard Denholt | +45 3079 8519 | [jlis@novonordisk.com](mailto:jlis@novonordisk.com) |
| Lars Borup Jacobsen | +45 3075 3479 | [lbpj@novonordisk.com](mailto:lbpj@novonordisk.com) |
| Daniel Bohsen | +45 3079 6376 | [dabo@novonordisk.com](mailto:dabo@novonordisk.com) |
| Frank Daniel Mersebach (US) | +1 609 235 8567 | [fdni@novonordisk.com](mailto:fdni@novonordisk.com) |

**References**

1. Buse J, *et al.* The fixed ratio combination of insulin degludec and liraglutide in a randomised controlled trial: a novel alternative to basal insulin in the management of type 2 diabetes. *Diabetes Care*. August 2014.