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**UK Medical media only**

**Phase 3a data demonstrates efficacy and tolerability of IDegLira (insulin degludec/liraglutide; Xultophy*®*) in adults with type 2 diabetes**

* *Adults with type 2 diabetes taking IDegLira had a significant reduction in blood glucose (measured by HbA1c) and a low rate of hypoglycaemia comparable to insulin degludec, as well as an added benefit of weight loss*
* *IDegLira helps patients who are managing their diabetes with basal insulin by providing an option to step up their treatment while avoiding additional injections*
* *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) was received for IDegLira in the EU on 24 July 2014*

**Gatwick, UK, 11 August 2014** –Today, *Diabetes Care* publishes phase 3a findings demonstrating a significantly greater glucose-lowering effect with IDegLira (insulin degludec/liraglutide; Xultophy®) compared to insulin degludec. People on IDegLira also experienced a low rate of hypoglycaemia, comparable to insulin degludec, and achieved a reduction in body weight when compared to treatment with basal insulin alone.[[1]](#endnote-1) The data are from the DUal Action of Liraglutide and insulin degludec in type 2 diabetes (DUAL™ II) trial investigating IDegLira, the first once-daily basal insulin (insulin degludec, Tresiba®▼)[[2]](#endnote-2) and GLP-1 receptor agonist (liraglutide, Victoza®)[[3]](#endnote-3) in one pen.

IDegLira demonstrated a mean HbA1c reduction of 1.9% from baseline, versus 0.9% with insulin degludec. Sixty percent of people treated with IDegLira achieved the HbA1c goal of less than 53mmol/mol (˂7.0%) compared to 23% treated with insulin degludec (p<0.0001). People treated with IDegLira had a significant mean weight loss of 2.7 kg from baseline compared to no change with insulin degludec (p<0.0001). Forty percent of the people treated with IDegLira, achieved the HbA1c goal with no confirmed hypoglycaemic episodes and with no weight gain, compared to 8.5% of people treated with insulin degludec (p<0.0001).

Commenting on the publication, Professor Anthony Barnett, Emeritus Professor of Medicine and Consultant Physician at the University of Birmingham and Heart of England NHS Foundation Trust, said: “Type 2 diabetes is a progressive disease which is associated with a significant personal and societal burden. Blood glucose control is critical in helping reduce the risk of long term diabetes complications which cause considerable morbidity and mortality and cost the NHS billions of pounds per annum. Any treatment which can help people with diabetes reach their glycaemic targets, while limiting side effects (particularly weight gain and hypoglycaemia), will be an important weapon in the fight against this complex condition.”

Control of HbA1c is a crucial target in diabetes management. In the United Kingdom (UK), the Quality and Outcomes Framework has set the HbA1c target as ≤7.5%.[[4]](#endnote-4) Nearly three quarters of people with type 2 diabetes on basal insulin regimens, in the UK, fail to reach less than 58mmol/mol HbA1c (≤7.5%) and are therefore at a greater risk of complications.[[5]](#endnote-5)-[[6]](#endnote-6)[[7]](#endnote-7),[[8]](#endnote-8) A one percentage point drop in HbA1c can lead to a 37% reduction in microvascular complications, a 14% reduction in myocardial infarctions and a 21% reduction in overall diabetes-related mortality.

Gwen Hall, Diabetes Specialist Nurse, Portsmouth Community Diabetes Service, noted: “Intensifying basal insulin regimens comes with additional risks for people with type 2 diabetes in terms of hypoglycaemia, weight gain and a potential increase in the number of daily injections they have to take. Similar concerns for health professionals may delay treatment intensification. The adverse effect on individual’s wellbeing, and the complexity of managing the increased insulin regimen and side effects, can be a major barrier to adherence to the treatment plan. The DUAL II™ findings suggest that IDegLira could simplify that treatment regimen while improving blood glucose levels without increasing the risks of side effects.”

There were no apparent differences between the treatment groups with respect to adverse events, and standard safety parameters during the trial.

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

IDegLira is a combination of insulin degludec (Tresiba®), a once-daily basal insulin analogue with a long duration of action, and liraglutide (Victoza®), the once-daily human GLP-1 receptor agonist, which is developed for the treatment of type 2 diabetes. In clinical trials, IDegLira was administered once-daily independently of meals and has shown consistent HbA1c reductions in insulin-naïve adults with type 2 diabetes and in type 2 diabetes adults inadequately controlled on basal insulin. 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-blind, multicentre trial conducted at 75 sites across seven 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 metformin with or without sulphonylureas/glinides. Sulphonylureas 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 blood glucose control (maximum dose for IDegLirais 50 dose steps).

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.co.uk.

### Further information

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**References:**

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2. . Tresiba® Summary of Product Characteristics (SPC). Bagsværd, Denmark, Novo Nordisk A/S; 2014. [↑](#endnote-ref-2)
3. . Victoza® Summary of Product Characteristics (SPC). Bagsværd, Denmark, Novo Nordisk A/S; 2014. [↑](#endnote-ref-3)
4. . doctors.net.uk. Diabetes NICE Clinical Guidelines 2012:Locally Adapted Guidelines http://www.doctors.net.uk/\_datastore/ecme/mod1101/Diabetes\_NICE\_clinical\_guidelines\_v02.pdf. Accessed: 07 August 2014. [↑](#endnote-ref-4)
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6. . International Diabetes Federation. Diabetes Atlas 2013. Available at: <http://www.idf.org/diabetesatlas>. Accessed: 15 July 2014. [↑](#endnote-ref-6)
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8. . Bethel, M and M Feinglos, Basal Insulin Therapy in Type 2 Diabetes. *J. Am. Board. Fam. Med*. 2005;18(3):199-204. [↑](#endnote-ref-8)