

## Industry update

**With so many ongoing advances in the management of diabetes, this section keeps you up to date with product-related developments and other relevant news**

### **NICE gives approval for Lucentis<sup>®</sup> therapy**

NICE has recommended that Lucentis<sup>®</sup> (ranibizumab) can be used as a treatment for visual impairment caused by diabetic macular oedema if the eye has a central retinal thickness of 400 µm or more at the start of the treatment, after Novartis submitted a revised patient access scheme and new drug data.

Barbara Young, Chief Executive of Diabetes UK, said: "We are delighted that NICE have reconsidered their previous decision, and that this draft guidance recommends that Lucentis<sup>®</sup> is made available on the NHS, as this would mean more people with diabetes would have a better opportunity to preserve and possibly improve their vision."

### **Tredaptive<sup>™</sup> therapy discontinued for dyslipidaemia**

MSD has announced that the company will suspend the availability of Tredaptive<sup>™</sup> worldwide, as its benefits are considered to no longer outweigh its risks. Tredaptive<sup>™</sup> is a modified-release nicotinic acid and laropiprant tablet used to treat adults with dyslipidaemia; however, preliminary data from the HPS2-THRIVE (Heart Protection 2—Treatment of HDL to Reduce the Incidence of Vascular Events) study, funded by MSD, found that participants taking Tredaptive<sup>™</sup> to regulate dyslipidaemia showed a statistically significant increase in the incidence of some types of non-fatal serious adverse events.

The recommendation is that physicians stop prescribing Tredaptive<sup>™</sup> and consider other therapies to achieve dyslipidaemia management goals; individuals taking Tredaptive<sup>™</sup> should not discontinue treatment without consultation with a healthcare professional.

### **Tresiba<sup>®</sup> and Ryzodeg<sup>®</sup>: Europe launch plans announced for new treatments for diabetes**

Novo Nordisk announced that the European Commission has granted marketing authorisations for Tresiba<sup>®</sup> (insulin degludec) and Ryzodeg<sup>®</sup> (insulin degludec combined with insulin aspart) for the treatment of diabetes in adults across all EU member states.

Tresiba<sup>®</sup> is a once-daily new-generation basal insulin analogue with an ultra-long duration of action. In studies where Tresiba<sup>®</sup> was compared with insulin glargine, the new formulation demonstrated a significantly lower risk of hypoglycaemia, while successfully achieving equivalent reductions in HbA<sub>1c</sub>. Further, with a duration of action beyond 42 hours, Tresiba<sup>®</sup> is the first basal insulin to offer individuals the possibility of adjusting the time of injection when needed.

Ryzodeg<sup>®</sup> contains the once-daily new-generation basal insulin degludec in a soluble formulation with insulin aspart. It can be administered once- or twice-daily with main meals. In a study where Ryzodeg<sup>®</sup> was compared with NovoMix<sup>®</sup> (biphasic insulin aspart), the new formulation also demonstrated a significantly lower risk of hypoglycaemia while achieving reductions in HbA<sub>1c</sub>.

---

*Novo Nordisk launched Tresiba<sup>®</sup> in the UK and Denmark in early 2013 and expects to launch it in other European markets throughout the rest of 2013 and 2014. Ryzodeg<sup>®</sup> is currently expected to be launched approximately 1 year after Tresiba<sup>®</sup>.*

### **Lyxumia<sup>®</sup> (lixisenatide) launched as the first once-daily prandial GLP-1 receptor agonist**

Sanofi has been granted marketing authorisation in Europe for Lyxumia<sup>®</sup> (lixisenatide). Lyxumia<sup>®</sup> is being launched as the first once-daily prandial glucagon-like peptide-1 (GLP-1) receptor agonist for the treatment of individuals with T2D. GLP-1 is a naturally occurring peptide hormone that is released within minutes after eating a meal; it is known to suppress glucagon secretion from pancreatic alpha-cells and stimulate glucose-dependent insulin secretion by pancreatic beta-cells.

The European Commission's decision to grant marketing authorisation for Lyxumia<sup>®</sup> was based on results from the GetGoal clinical programme, which included 11 clinical trials and involved more than 5000 individuals with T2D; 706 individuals were treated with Lyxumia<sup>®</sup> on top of basal insulin and in combination with oral antidiabetes medications in three trials.

The clinical programme showed that Lyxumia<sup>®</sup> demonstrated significant reductions in HbA<sub>1c</sub>, a pronounced post-prandial glucose-lowering effect and a beneficial effect on body weight in adults with T2D. GetGoal results also showed that Lyxumia<sup>®</sup> had a favourable safety and tolerability profile in most individuals, with only mild and transient nausea and vomiting (the most common adverse events observed in GLP-1 receptor agonists) and a limited risk of hypoglycaemia.

Dr Bo Åhrén, Professor of Clinical Metabolic Research at Lund University, Sweden, commented:

"Lyxumia<sup>®</sup> in combination with oral and/or basal insulin therapies can play a key role in meeting the important need to maintain HbA<sub>1c</sub> targets for people with T2D."