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® therapy

NICE has recommended that Lucentis® (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Executive of Diabetes UK, said: "We are delighted that NICE have reconsidered their previous decision, and that this draft guidance recommends that Lucentis® is made available on the NHS, as this would mean more people with diabetes would have a better opportunity to preserve and possibly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™ therapy discontinued for dyslipidaemia

MSD has announced that the company will suspend the availability of Tredaptive™ worldwide, as its benefits are considered to no longer outweigh its risks. Tredaptive™ 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™ 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™ and consider other therapies to achieve dyslipidaemia management goals; individuals taking Tredaptive™ should not discontinue treatment without consultation with a healthcare professional.

Tresiba® and Ryzodeg®: Europe launch plans announced for new treatments for diabetes

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

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

Ryzodeg® 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® was compared with NovoMix® (biphasic insulin aspart), the new formulation also demonstrated a significantly lower risk of hypoglycaemia while achieving reductions in HbA_{1c}.

Novo Nordisk launched Tresiba® 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® is currently expected to be launched approximately 1 year after Tresiba®.

Lyxumia® (lixisenatide) launched as the first once-daily prandial GLP-1 receptor agonist

Sanofi has been granted marketing authorisation in Europe for Lyxumia® (lixisenatide). Lyxumia® 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® 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® on top of basal insulin and in combination with oral antidiabetes medications in three trials.

The clinical programme showed that Lyxumia® demonstrated significant reductions in HbA_{1c}, a pronounced post-prandial glucose-lowering effect and a beneficial effect on body weight in adults with T2D. GetGoal results also showed that Lyxumia® 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 Ahrén, Professor of Clinical Metabolic Research at Lund University, Sweden, commented:

"Lyxumia® in combination with oral and/or basal insulin therapies can play a key role in meeting the important need to maintain HbA_{1c} targets for people with T2D."