Industry DIGEST

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

Change in the terms of marketing authorisation for Levemir®

Levemir[®] (insulin determir) has had an update in the summary of product characteristics by the Committee for Medicinal Products for Human Use (CHMP) and the European Medicines Agency. It can now be used with all available glucagon-like peptide 1 receptor agonists.

The CHMP adopted a positive opinion recommending a change to the terms of the marketing authorisation for Levemir[®]: "Levemir can be used alone as the basal insulin or in combination with bolus insulin. It can also be used in combination with oral antidiabetic medicinal products and/or GLP-1 receptor agonists...". The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

Toujeo[®] approved in Europe

The European Commission have granted marketing authorisation in Europe for Toujeo[®] (insulin glargine [rDNA origin] injection, 300 U/mL), and thus approval for the treatment of type 1 and type 2 diabetes in the European Union. Produced by Sanofi, Toujeo[®] is a next-generation basal insulin.

The European Commission's decision to grant marketing authorisation is based on results from the EDITION clinical trial program, a series of worldwide Phase III studies evaluating the efficacy and safety of Toujeo® compared with Lantus® (insulin glargine [rDNA origin] injection, 100 U/mL) in more than 3500 adults with type 1 or type 2 diabetes who had inadequate glycaemic control on their current therapy.

Ozurdex[®] for diabetic macular oedema

NICE has proposed the use of Ozurdex® (dexamethasone 0.7 mg intravitreal implant in applicator) as a treatment for diabetic macular oedema (DMO) in people who have an artificial lens and who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.

The recommendation for Ozudex[®] extends to Scotland, but, as yet, it is not funded for people who have their natural lens.

Ozurdex[®] manufactured by Actavis plc is a biodegradable intravitreal implant that releases dexamethasone to suppress inflammation, which plays a key role in the development of DMO, over an extended period of time.

AACE/ACE updated practical guidelines

The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) have issued new, more comprehensive guidelines outlining optimal care for people with type 2 diabetes.

The publication includes expansive clinical practice and an updated illustrated algorithm to assist healthcare professionals with the medical management of people with T2D. It also includes information on vaccinations, cancer risks, prediabetes management, sleep disorders and depression, and updates guidelines on selecting antihyperglycaemic agents and managing hypertension, nephropathy and hypoglycaemia.

Combined empagliflozin and metformin receives positive opinion

The Committee for Medicinal Products for Human Use of the European Medicines Agency has adopted a positive opinion on a combined product for type 2 diabetes containing empagliflozin and metformin, recommending the marketing authorisation be granted. The product is to be known as Synjardy[®] (Boehringer Ingelheim).

Synjardy[®] will be available as a film-coated tablet in four different doses of empagliflozin (a sodium—glucose co-transporter 2 inhibitor) and metformin.

If approved, Synjardy® will be indicated for the treatment of adults as an adjunct to diet and exercise to improve glycaemic control for people who are inadequately controlled on other treatments and who are already being treated with the combination of empagliflozin and metformin as separate tablets.

3D printing technique to treat type 1 diabetes

A 3D printing technique known as bioplotting could hold the key to islet transplantation for T1D as published in the journal *Biofabrication*.

Still in early development, the paper describes how clusters of islets of Langerhans have successfully been 3D printed into a scaffold, which it is hoped will provide an efficient and effective delivery system for islet transplantation.

The islets were embedded into scaffolds made from an alginate/gelatin mixture with a cross-linked structure and showed full functionality once extracted. The islet cells were included in the liquid hydrogel mixture during printing to create the porous 3D scaffold. Future research from the team will include how best to recreate an optimal islet micro-environment for the donor islets to thrive.