EMERGENT THERAPIES

ABATACEPT SHOWS PROMISE IN EARLY RA

The biological agent abatacept, currently used in the treatment of moderate to severe rheumatoid arthritis (RA), has shown significant benefit in the treatment of patients with early RA, according to data from a Phase 3b trial.

Findings from the trial, known as AVERT, showed that patients with early rheumatoid arthritis (RA) treated with abatacept in combination with methotrexate (MTX) achieved significantly higher rates of remission at 12 months compared with treatment with standard of care agent MTX (60.9% vs. 45.2%, respectively)

The AVERT trial also assessed maintenance of remission following the withdrawal of all RA drug therapy, including abatacept, MTX and steroids. A small but statistically significantly higher number of patients treated with abatacept plus MTX, versus MTX alone, for 12 months maintained remission six months after treatment withdrawal.

ALPOSTRADIL NOW AVAILABLE AS TOPICAL CREAM

The first cream to come onto the market for treatment of erectile dysfunction is now available in the UK.

The cream, Vitaros (topical alprostadil) will be prescribable for men aged over 18 and offers an alternative non-invasive treatment option to the 2.3 million in the country suffering from ED.

European approval was based on Phase 3 trial data showing that almost 40% of men using topical alprostadil experienced a clinically significant improvement in their erection function compared with 21% of men using placebo.

The cream comes in a single use, applicator and, the data shows, can produce an erection within 5-30 minutes.

CHMP APPROVES AFLIBERCEPT FOR DMO

The European Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of the biological aflibercept injection solution for the treatment of visual impairment due to diabetic macular oedema (DMO).

The recommendation is based on data from two Phase 3 trials, VIVID-DME and VISTA-DME, which showed 2mg aflibercept injection (branded Eylea) every other month achieved rapid and sustained visual acuity gains when compared with laser photocoagulation treatment.

DMO, a serious eye condition affecting people with diabetic retinopathy, is the commonest cause of blindness among people of working age in the developed world.

Aflibercept treatment begins with a monthly injection into the eye for five consecutive months, followed by one every two months. After the first 12 months of treatment, injections can be spaced out even further.

The most frequent adverse events in clinical trials included conjunctival haemorrhage, eye pain, and vitreous floaters, along with hypertension and nasopharyngitis.

Aflibercept was licensed last year in the UK for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO).

CLINICAL RESEARCH

TRIAL RESULTS SHOW PROMISE FOR NEW ONCE-WEEKLY ANTI-DIABETIC

Newly released results from two Phase 3 trials have shown that treatment with the investigational once-weekly anti-diabetic dulaglutide elicited superior reductions in HbA1c compared with insulin glargine, with a lower risk for hypoglycemia.

Dulaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist being studied for the treatment of type 2 diabetes. Results of the two studies – part of the five-trial AWARD programme – were presented at the 74th American Diabetes Association Scientific Sessions in June.

Data from the AWARD-2 trial, which evaluated the safety and efficacy of two doses of once-weekly dulaglutide compared with insulin glargine as add on to combination therapy with sulfonylurea and metformin, showed that once-weekly dulaglutide 1.5 mg provided superior blood sugar control at 52 and 78 weeks.

Significantly more dulaglutide 1.5mg-treated patients reached target HbA1c levels of less than 7%. Both doses of dulaglutide were associated with sustained weight loss, while insulin glargine showed weight gain.

Results from the AWARD-4 trial showed that once-weekly dulaglutide 1.5 mg and 0.75 mg combined with mealtime insulin lispro provided superior blood sugar control at 26 and 52 weeks compared with the traditional basal/bolus combination of insulin glargine and mealtime insulin lispro.

Adverse events were similar for dulaglutide-treated patients in both studies. The most frequently reported events were gastrointestinal-related, including nausea, diarrhoea and vomiting.

If approved, dulaglutide will be marketed under the brand name Trulicity.

TECHNOLOGY APPRAISAL

SECOND SGLT2I APPROVED FOR T2D

NICE has issued new final guidance recommending canagliflozin (Invokana), as an option for treating some people with type 2 diabetes. This brings to ten the number of NICE-approved anti-glycaemic agents for people with type 2 diabetes.

Canagliflozin is an oral, once-daily medication, the second in a new class of drugs known as sodium glucose co-transporter (SGLT-2) inhibitors (*see page 29*). It is recommended when used in combination with other anti-diabetic drugs, including insulin, for the treatment of type 2 diabetes.

NICE CHANGES TACK ON PRASUGREL

Following a review of its guidance on the anti-platelet agent prasugrel (Efient), NICE has published draft guidance recommending the drug in combination with aspirin for preventing blood clots in people who have acute coronary syndromes (ACS) and who are also undergoing percutaneous coronary intervention.