Ellex 2RT™ for early age-related macular degeneration

TECHNOLOGY

Ellex Retinal Rejuvenation Therapy or Ellex 2RT™, developed by Ellex, is a nanosecond laser therapy that stimulates healing in the eye. Ellex 2RT™ is intended to delay or stop disease progression in early age-related macular degeneration (eAMD), before patients experience a significant loss of vision.

Ellex 2RT™ uses short pulses of nanosecond (low level) laser energy to stimulate the retinal pigment epithelium (RPE), which is responsible for transporting nutrients to and waste from the retinal photoreceptors (specialised cells in the retina that respond to light). According to the company, this treatment stimulates a process of cellular rejuvenation, reversing impaired transport mechanisms, without causing damage to the retina.

The procedure lasts around 15 minutes and is performed by an ophthalmologist. Local anaesthetic drops are applied into the conjunctival sac of the eye prior to the treatment. The company states that the treatment effect persists for at least 12 months and re-treatment may be beneficial in some cases.

Ellex 2RT™ was CE marked for diabetic macular oedema in July 2012. The company expects CE marking specifically for eAMD in early 2014 and UK launch is currently anticipated in 2014.

POTENTIAL FOR IMPACT

AMD is a painless eye condition that leads to the gradual loss of central vision. Early AMD is diagnosed by the presence of medium sized drusen (yellow or white material that builds up under the retina). People with early AMD usually do not have significant vision loss.

AMD in the more advanced stages is the leading cause of visual impairment amongst the elderly. About 5 in 100 people aged over 65 and about 1 in 8 people aged over 80 have
AMD severe enough to cause serious visual loss. Visual loss can occur within months or over many years, depending on the type and severity of AMD. Visual loss caused by AMD cannot normally be reversed.

There are two main types of advanced AMD, ‘wet’ and ‘dry’. In the early disease stages of AMD it is unclear whether patients will develop choroidal neovascularisation (wet) or geographic atrophy (dry) and in some patients it will be both.

Choroidal neovascularisation involves the growth of new blood vessels under the retina. These vessels can leak fluid and blood, which may lead to swelling and damage of the macula. Choroidal neovascularisation is a major cause of visual loss. There are treatments available that may halt or delay the progression of visual loss in some people with wet AMD, such as anti-vascular endothelial growth factor (anti-VEGF) drugs (ranibizumab and aflibercept), photodynamic therapy and laser photocoagulation.

Geographic atrophy is less common and is characterised by accumulations of drusen between the retina and the choroid (vascular layer of the eye). The retina can become detached, with subsequent vision loss. There are no specific treatment options available as yet.

According to the company, Ellex 2RT™ is likely to be more effective in patients with eAMD because patients that have progressed to the advanced stages of AMD may have severely compromised retinal structures and reversal may be difficult or impossible.

If proven to be clinically effective, Ellex 2RT™ may provide a new treatment option for eAMD and may be able to delay or stop disease progression in the early stages of AMD, before patients experience significant vision loss. If this technology is effective in delaying or stopping disease progression, it will bring great benefits to patients and carers and reduce costs associated with supporting patients in the community. The potential impact of Ellex 2RT™ on the health service will be dependent on its comparative efficacy, the safety profile and the number of patients who are suitable for treatment.

**EVIDENCE**

**RELATED PUBLICATIONS**


COMPLETE UNPUBLISHED STUDIES

Efficacy and safety of retinal rejuvenation using Ellex 2RT laser in age-related maculopathy (RETIPLACE trial)

ONGOING STUDIES

ClinicalTrials.gov. Laser intervention in early age-related macular degeneration (LEAD) study.

COMPANY INFORMATION

Ellex 2RT for AMD study.

INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.