

ASX RELEASE

Ellex Medical Lasers Limited (ASX:ELX)

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Topic: Ellex Achieves Key Milestones in Clinical Trial Program for 2RT



Adelaide, Australia, 4 September 2013 – Ellex Medical Lasers Limited (ASX:ELX), a pioneer in medical technologies for the diagnosis and treatment of eye disease, today announced several key milestones in the Company’s clinical trial program for its proprietary Retinal Rejuvenation Therapy (2RT™) in the treatment of Early Age-Related Macular Degeneration (AMD). Currently, there are no approved treatments for the early form of AMD, which represents a considerable market opportunity for Ellex.

Ellex is pleased to advise that recruitment for the “Laser Intervention in Early Age-Related Macular Degeneration” (LEAD) trial recently surpassed 50 patients across two clinical sites at the Centre for Eye Research Australia (CERA) in Melbourne and at Marsden Eye Clinic in Sydney.

Two further sites have since been established at Eye Surgery Associates (Associate Professor Wilson Heriot) in Melbourne and at Lions Eye Institute in Perth. Patient recruitment has commenced at Eye Surgery Associates and will soon commence at Lions Eye Institute.

The recent US FDA 510(k) approval for 2RT in the treatment of diabetic eye disease has cleared the pathway to extend the 2RT clinical trial program to the USA. The establishment of additional clinical sites over the coming months is expected to further accelerate patient recruitment efforts.

The LEAD trial is a multi-centre, double-blind, randomised, controlled clinical trial. Approximately 300 patients with bilateral high-risk early AMD (AREDS simplified severity score of 2-4) over 50 years of age will be recruited in the trial. Patients in the treatment group will undergo the 2RT procedure in one eye, with treatment to be repeated at six-monthly intervals, as required under the protocol design. Patients in the control group will undergo a sham procedure.

The primary endpoint of the LEAD trial is progression to advanced AMD in the treated eye, as assessed by ocular examination, colour fundus photography, Ocular Coherence Tomography (OCT) and fluorescein angiography at 36 months post initial intervention. The secondary endpoint is progression to advanced AMD in the non-treated eye.

The LEAD trial was launched in November 2012 to validate the clinical efficacy of 2RT™ in the treatment of the early stages of AMD and is led by Professor Robyn Guymer, MB, BS, PHD, FRANZCO, Head of Macular Research at CERA.

The complete trial protocol for the LEAD trial is available at the Clinical Trials Registry (ClinicalTrials.gov Identifier: NCT01790802) and at www.ellex.com.

“The establishment of additional sites in Australia is a significant milestone in our clinical development program for 2RT. We are also in discussion with several other potential sites, including two in the USA and three in Europe, with ethics and regulatory approval arrangements underway,” commented Professor Guymer.

The LEAD trial follows a successful pilot study by CERA in 2011 (ACTRN12609001056280), which completed two-year patient follow-up in December 2012. The results of this pilot study are expected to be published in the near future.

The LEAD trial is partially supported by funding from the National Health and Medical Research Council and the Bupa Foundation. The remaining clinical sites are funded independently. Ellex is providing technical and equipment support to all clinical sites.

Commenting on the future outlook for 2RT™, Ellex CEO Tom Spurling said: “Patient recruitment is a key focus for the clinical research teams over the coming year. From a commercial standpoint, securing CE Marking for 2RT in the treatment of early AMD will be a principal goal for our business.”

CERA is currently seeking trial participants in Melbourne, Sydney and Perth. Ideal participants are those aged between 50 and 95 with good vision (6/12 or better in each eye) and with a diagnosis of high-risk, intermediate AMD. The treatment is not suitable for people who have already developed AMD in its advanced stages, either the dry or wet form. Individuals who think that they may be suitable for inclusion in the LEAD trial should contact their eye care professional.

ABOUT AMD

A progressive disease affecting the central region of the eye called the macula, AMD is the leading cause of blindness in the developed world. In Australia, AMD affects one in seven Australians over the age of 50 (Source: report prepared for Macular Disease Foundation, Access Economics). The economic impact and cost of AMD is high, and is estimated to directly cost the Australian community more than AU\$2.6 billion annually (Source: CERA). Current treatment options for AMD only address advanced or end-stage complications associated with the disease in some patients. In contrast, 2RT™ offers the potential to apply treatment earlier in the disease process, before significant vision loss has occurred, with the aim of slowing or reversing the process of degeneration, and hence delaying or preventing late stage disease. This would offer a major breakthrough in treatment strategy.

ABOUT ELLEX

Ellex Medical Lasers Limited (ASX:ELX) is a pioneer in the development of medical technologies for the diagnosis and treatment of eye disease. Since 1985, Ellex has evolved from a manufacturing company of primarily OEM products to direct marketing of its own branded products through subsidiaries in the United States, Japan, Germany and Australia, and a network of distribution partners in more than 100 countries. Today, more than 20,000 Ellex laser and imaging systems are used worldwide in the fight against blindness. In more recent times, Ellex has diversified its product range to include distribution of a number of complementary third-party ophthalmic products.

For additional information about Ellex and its products, please visit www.ellex.com.

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