



8 July 2019

## Fourth Year Post-LEAD Review Shows Sustained Positive Ellex 2RT® Treatment Benefits for Selected iAMD Patients

**Adelaide, Australia, 8 July 2019** – Ellex Medical Lasers Limited (ASX:ELX; OTCQX: ELXMY, ELXMF), a world leader in medical technologies for the diagnosis and treatment of eye disease, is pleased to announce the results of the four year patient follow up from the LEAD clinical trial, investigating the use of Ellex 2RT® Retinal Rejuvenation Therapy in the treatment of intermediate age-related macular degeneration (iAMD).

In September 2018 Ellex reported the results of LEAD<sup>1</sup>, which was the first time any form of laser intervention has shown a promising clinical response in a large group of well-defined iAMD patients prior to progression to vision impairing late AMD. The trial demonstrated that for selected patients who did not have coexistent reticular pseudodrusen (RPD) at the commencement of the trial (76% of 292 patients enrolled), intervention with 2RT resulted in a significant treatment effect ( $p=0.002$ ) and a clinically meaningful four-fold or 77% reduction in the rate of progression from iAMD to late AMD versus sham (placebo) treatment at 36 months (Hazard Ratio, HR=0.23). RPD is a key biomarker of retinal pigment epithelium (RPE) dysfunction and has a high association with progression to late AMD.

Of the 292 participants who were randomised into the LEAD study, 183 (63%) attended a 4<sup>th</sup> year post-LEAD follow up visit. This observational study showed that 2RT therapy has an enduring rejuvenative impact on the retina. The data showed very little change in the clinical parameters the study investigators observed and reported at 36 months, despite no additional 2RT treatment for these patients beyond 30 months. At 48 months in patients without coexistent RPD at baseline, there was a 72% reduction in the rate of progression to late AMD versus sham, which remains clinically significant (statistical significance HR=0.28,  $p=0.002$ ).

Prof. Andrea Cusumano, MD, PhD, a leading retinal specialist in Italy who has treated a number of patients with 2RT said “The durability of the 2RT treatment response well beyond the 30 months when selected iAMD patients last received this non-invasive therapy is compelling in light of current invasive treatment modalities, which are only approved for wet forms of late AMD and comprise ocular injections that need to be routinely performed every 8-10 weeks to limit further deterioration in visual acuity and help preserve retinal function. Given the excellent safety profile of 2RT, it would be interesting to assess whether additional therapeutic benefit would be conferred by treatment beyond the 30 months of the study.”

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<sup>1</sup> Guymer RH, Wu Z, Hodgson LAB, et al. Sub-Threshold Nanosecond Laser Intervention in Age-Related Macular Degeneration: The LEAD Randomized Controlled Clinical Trial. *Ophthalmology*. 2018.

Mr. Ged Wallace, Chief Executive Officer of Ellex commented “These data once again highlight the significant restorative effects of 2RT on retinal health in selected patients with iAMD, resulting in a material delay in the time it takes for the disease to progress to late forms of the disease, where vision is impacted and patient quality of life declines markedly.”

The LEAD data now clearly highlights that Ellex 2RT offers the potential to intervene earlier in the disease process to improve retinal function and slow the rate of progression of AMD through this novel, safe and non-invasive treatment intervention.

These participants in the post LEAD follow-up study will be followed for a further 12 months (cumulatively 5 years of total patient monitoring under trial conditions and follow up), at which time a scientific publication by the study investigators is expected to be submitted to a major medical journal.

**- ENDS -**

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#### ABOUT THE LEAD CLINICAL TRIAL

The Laser Intervention in Age-Related Macular Degeneration (LEAD) clinical trial (Australian New Zealand Clinical Trials Registry ACTRN12612000704897 and [clinicaltrials.gov](http://clinicaltrials.gov) NCT01790802) was a double-masked, randomised, sham-controlled trial conducted over six sites: five in Australia and one in Northern Ireland.

There were 292 participants in the trial, which completed recruitment in April 2015. Participants recruited into the trial were 50 years or older, with a diagnosis of AMD and having at least one large drusen in both eyes and no evidence of atrophy as measured by multi-modal imaging (MMI). These phenotypic characteristics met the definition of iAMD.

Participants were randomly assigned 1:1 to the Ellex 2RT<sup>®</sup> treatment group or a sham treatment group. Participants received treatment as a standardised series of 12 laser spots applied to the macular region of the treated eye. Each participant was reviewed at six-monthly intervals over a total period of 36 months. Repeat treatment was conducted at each 6-month review for participants who remained eligible for retreatment.

#### ABOUT ELLEX 2RT<sup>®</sup>

Ellex 2RT<sup>®</sup> is a non-thermal laser therapy that stimulates a natural, biological healing response in the eye and has demonstrated potential as an intervention which can positively influence early stage Age-Related Macular Degeneration.

## ABOUT ELLEX

Ellex designs, develops, manufactures and sells innovative product that help eye surgeons around the world to effectively and efficiently treat eye disease. Ellex is a world leader in this field. Headquartered in Adelaide, Australia, Ellex has ophthalmic lasers and devices that treat glaucoma, retinal disease primarily caused by diabetes, secondary cataract and vitreous opacities, as well as age-related macular degeneration. Manufacturing is carried out in Adelaide, Australia and Fremont, California. Sales and service directly to eye surgeons is conducted via subsidiary offices in Minneapolis, Lyon, Berlin and Tokyo. A network of more than 50 distribution partners around the world services other markets.

**For additional information about Ellex and its products, please visit [www.ellex.com](http://www.ellex.com)**

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