ASX RELEASE

Ellex Medical Lasers Limited (ASX:ELX)

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Topic: Ellex Announces Interim Review for 2RT® Clinical Trial

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Adelaide, Australia, 30 May 2016 – Adelaide, Australia, 30 May 2016 – Ellex Medical Lasers Limited (ASX:ELX), a world leader in medical technologies for the diagnosis and treatment of eye disease, today announced the completion of an interim review of the initial participants in a clinical trial of its 2RT® retinal rejuvenation laser as a treatment for intermediate stage age-related macular degeneration (AMD). The interim review was conducted without unmasking to maintain ongoing trial integrity. As a result of this interim review the trial will continue its full course through to at least April 2018.

"We are very pleased to report that the trial has passed this important milestone and will continue. This milestone was achieved based on the recommendation from the lead investigator on the trial. The analysis reported a meaningful difference in drusen progression and retinal sensitivity between the two groups, one of which received sham treatment and the other 2RT treatment. It also demonstrated a good safety profile," commented Ellex CEO Tom Spurling.

Background of the clinical trial

The Laser intervention in Early Age-related macular Degeneration (LEAD) trial is a double-masked, randomised, sham-controlled trial being conducted over six sites: five in Australia and one in Northern Ireland.

The lead investigator of the LEAD trial is Professor Robyn Guymer, MBBS, PhD, FRANZCO, a world-leading retinal professor who is based at the Centre for Eye Research Australia (CERA) in Melbourne, Australia.

There are 292 participants in the trial. The 292nd participant was recruited and randomised in April 2015.

Participants have been randomly assigned to the 2RT® laser or sham treatment groups (145 participants in "Group 1" and 147 participants in "Group 2"). Participants received treatment as a standardised series of 12 laser spots applied to the macula region of the treatment ("study") eye; a conservative dose designed to minimise the possibility of harm to patients. Each participant is being comprehensively reviewed at six-monthly intervals over a total period of 36 months. The 36-month review period will be completed for the last randomised patient in April 2018. Repeat treatment is being conducted at each 6 month review if the participant remains eligible for retreatment.

The interim analysis revealed that the randomisation has produced two groups which are very well matched in terms of AMD characteristics and potential variables (such as smoking status) that might influence the outcome of the disease.

Interim Review Process

CERA is conducting the trial and Ellex is progressively providing funding to support the trial. Under the funding agreement, CERA agreed to conduct an interim review without unmasking the trial randomization code to determine if there were differences developing between the two groups which would indicate if it was sensible to continue with the study as planned. The review was designed to maintain the statistical integrity of the trial and therefore does not disclose which of the two groups received 2RT® treatment versus the sham treatment.

The review was conducted on the subset of participants that had reached 18 months follow up (approximately 150 participants) at the end of January 2016. The interim review therefore provides information on the first 150 participants at 18 months into the 36-month follow-up period.

Interim Review Results

The interim review revealed:

(i) There was no meaningful difference in the incidence of neovascularization (CNV, see footnote below) between groups giving reassurance that the 2RT® laser was not leading to an early increase in neovascularization as had appeared to be the case in previous thermal laser trials (see footnote below).

(ii) There was no meaningful difference in the incidence of geographic atrophy (GA, see footnote below) between groups, thereby giving reassurance that the 2RT® laser was not dramatically increasing the rate of GA.

(iii) There was a meaningful difference between the two study groups in that one of the two groups demonstrated a reduction in drusen load and an improvement in retinal sensitivity. The usual consequence of drusen regression is the development of geographic atrophy. This does not seem to be the case in this trial, as drusen load reduction was not accompanied by loss of retinal sensitivity. In addition, the number of geographic atrophy cases did not differ between groups, reinforcing the safety aspect of the treatment.

Commentary

- Professor Guymer has recommended to Ellex that the trial continue.
- The LEAD Trial Safety Committee, an independent review board overseeing safety aspects of the trial, has recommended that the trial continue without modification.
- At this early stage in the trial it was not expected that there would be a statistical difference in the number of participants that reached end-stage AMD.
- The recommendation from Professor Guymer, the meaningful difference in drusen progression and retinal sensitivity, along with the decision of the LEAD Trial Safety Committee, suggests that continuation of the trial is worthwhile.
- In order to maintain the statistical integrity of the trial the interim review does not disclose whether the sham or the laser treatment group showed better retinal sensitivity or lower drusen volume or area.

ABOUT AMD

Age-Related Macular Degeneration (AMD) is the leading cause of blindness in the developed world and affects one in seven Australians over the age of 50 (Macular Disease Foundation, Access Economics). Advanced AMD is categorized as either Geographic Atrophy (GA or “so called “Dry AMD”) or Choroidal Neovascularisation (CNV or so called “Wet AMD”). GA, or Dry, AMD is associated with atrophic cell death of the central retina or macula. CNV, or Wet AMD, is caused by growth of abnormal blood vessels under the macula. To date, no specific treatment exists to halt the progression of AMD to its advanced stage. In contrast 2RT® offers the potential to apply treatment earlier in the disease process, with the aim of slowing or reversing the process of degeneration, and hence delaying, or preventing, late stage disease.

ABOUT 2RT®

2RT® is a non-thermal laser that stimulates a natural, biological healing response in the eye and has demonstrated potential as an intervention and positively influencing intermediate Age-Related Macular Degeneration (AMD). Unlike conventional retinal laser therapy, which can cause permanent collateral damage to the sensitive structures of the eye, 2RT® protects the retina from thermal damage.

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

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