

ASX RELEASE

Ellex Medical Lasers Limited (ASX:ELX)

Adelaide, Australia

Date: 18 November 2014

Release: Immediate

Topic: Further Positive Scientific and Clinical Research Validating the Clinical Efficacy of 2RT for Early AMD Published



18 November 2014, Adelaide, Australia, – Ellex Medical Lasers Limited (ASX:ELX), a pioneer in medical technologies for the diagnosis and treatment of eye disease, today announced that additional positive scientific and clinical research on the therapeutic and safety profile of the Company’s proprietary Retinal Rejuvenation (2RT™) technology has been published in the peer-review journal ‘Federation of American Societies for Experimental Biology’ (FASEB).

The scientific and clinical research incorporates two sets of work: 24-month clinical data, which is a follow-up to the 12-month pilot study “2RT for Early AMD” (ACTRN 1260900E1056280), and scientific work on the impact of 2RT™ in two exenterated (surgically removed) human eyes and a series of animal eye models.

Clinical Research Demonstrates Sustained Reduction in Drusen Over 24-Month Period

The 24-month clinical data, conducted by Professor Robyn Guymer, MB, BS PhD, FRANZCO, at the Centre for Eye Research Australia (CERA), demonstrated the potential of 2RT™ to reverse the accumulation of drusen in patients with high-risk early AMD over a 24-month period.

The presence of drusen, small fatty deposits in the eye, is a key risk factor for AMD progression.

51 patients with intermediate AMD underwent treatment with 2RT™ in one eye. The drusen area in each eye was graded at baseline, and post-treatment at 12 months and 24 months respectively. Changes in drusen area in the treated eye were evaluated against a natural history AMD cohort of similar age range and clinical severity. 2RT™ reduced drusen area in 35-40% of treated eyes at 24 months, compared to 5-11% of eyes in the natural history AMD cohort.

“Importantly, no patients in the 24-month pilot study progressed to Wet AMD. This is further evidence which suggests that 2RT may be a potential viable intervention for those at risk of vision loss from AMD,” said Tom Spurling, Ellex CEO.

Scientific Research Validates Mechanism of Action

The scientific research evaluated two exenterated human eyes, which underwent treatment with 2RT™ just prior to being removed, and a series of mouse eye models. A number of criteria were assessed, including retinal damage profiles, neuronal effect and inflammatory response. Conducted at the University of Melbourne, Australia, by Erica L. Fletcher, MScOptom, PhD, the research demonstrated the ability of 2RT™ to reverse the pathological and molecular profiles of AMD without resulting in retinal damage .

“Our research suggests that nanosecond laser therapy can improve the health of the retinal pigment epithelium (RPE), a matrix of cells located at the back of the eye which play a critical function in maintaining eye health,” commented Associate Professor Fletcher.

“By improving the function of the RPE cells, we may be able to limit the progression of AMD and prevent its advancement to the late stage of the disease, known as Wet AMD.”

The findings from the human eyes corroborate those from the mouse eye models.

“This is the first time we have been able to demonstrate the mechanism of action of 2RT in human retina explants,” said Associate Professor Fletcher.

According to Mr. Spurling, the research by Associate Professor Fletcher and colleagues is of major significance in documenting the mechanism of action of 2RT™.

“This important work has helped to elucidate the process by which 2RT alters the disease state in AMD patients and has enabled us to better understand how the treatment could be used in clinical practice,” said Mr. Spurling.

The peer-review publication “Nanosecond laser therapy reverses pathological and molecular changes in age-related macular degeneration without retinal damage” will assist the Company’s current controlled commercial roll out of 2RT™ in key markets. It also supports the focus of the ongoing multi-centre double-blind, randomised, controlled “Laser Intervention in Early AMD” (LEAD) trial. The abstract can be viewed online at <http://www.fasebj.org/content/early/2014/11/12/fj.14-262444.abstract>.

ABOUT AMD

Age-Related Macular Degeneration (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 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.

AMD affects the central area of the retina called the macula and is the leading cause of blindness in the developed world. Globally, the early form of the disease accounts for up to 80% of all cases of AMD. To date, no treatment exists to halt the progression of AMD to its advanced stage, which is associated with severe vision loss.

ABOUT 2RT

Retinal Rejuvenation Therapy (2RT™) delivers nanosecond pulses of laser energy to stimulate a natural, biological healing response in the eye to stimulate a process of cellular rejuvenation to preserve and/or improve functional vision, reducing disease progression. These nanosecond pulses generate a response by retinal pigment epithelium (RPE) melanosomes, without causing heat to escape beyond the RPE cell walls. These pulses cause damage to the internal cell structure only: they do not break the cell’s outer membrane. This process of regeneration acts to rejuvenate the entire transport mechanism of the retina, improving visual function and reducing disease progression. This breakthrough approach retains the therapeutic effect of laser therapy whilst eliminating the thermal tissue damage inherent in conventional retinal photocoagulation laser treatment.

2RT™ has a CE Mark (Conformité Européenne) and is included on the Australian Register of Therapeutic Goods (ARTG) for the treatment of early AMD.

For additional information about 2RT, please visit www.ellex.com/2RT

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. With more than 20,000 systems delivered to market, Ellex has evolved since 1985 from a manufacturing company of primarily OEM products, to direct marketing of its own branded products through subsidiaries in the United States, Japan, France, Germany and Australia, and a network of distribution partners in more than 100 countries. In recent years, Ellex has diversified its product range beyond lasers and ultrasound equipment to include distribution of a number of complementary third-party ophthalmic products. On 31 December 2013 Ellex acquired the Canaloplasty microcatheter-based glaucoma surgical treatment from iScience Interventional, Inc.

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

For further information on Ellex, please contact:

Tom Spurling, CEO
Ellex Medical Lasers Limited
82 Gilbert Street, Adelaide, SA, 5000
W +61 8 8104 5293 | M +61 417 818 658
tspurling@ellex.com

Victor Previn, Chairman
Ellex Medical Lasers Limited
82 Gilbert Street, Adelaide, SA, 5000
W +61 8 8104 5200 | M +61 414 661 994
vprevin@ellex.com

Maria Maieli, Company Secretary
Ellex Medical Lasers Limited
82 Gilbert Street, Adelaide, SA, 5000
W +61 8 8104 5200
mmaieli@ellex.com

For media enquiries, please contact:

Kate Hunt, Corporate Communications Manager
Ellex Medical Lasers Limited
82 Gilbert Street, Adelaide, SA, 5000
W +61 404 080 679
khunt@ellex.com