



AlphaRET

Clinical Update: 2RT[®] Improves Retinal Function in Cases of Intermediate AMD

Fremont, California, 16 November 2020 – Nova Eye Medical Limited and its subsidiary AlphaRET Pty Ltd (AlphaRET) today announce clinical results which demonstrate the ability of the Company's proprietary 2RT[®] nano-pulse ophthalmic laser therapy to positively impact the function of the retinal pigment epithelium and photoreceptors in the treatment of intermediate age-related macular degeneration (AMD).

This is the first time that a treatment has been shown to improve retinal function in patients with intermediate AMD.

The leading cause of blindness in industrialized countries, AMD is a chronic eye disease that can result in distorted vision and/or a loss of central vision. It most frequently affects people over fifty years of age.

The development of 2RT[®] commenced in 2005 to address the growing need to treat AMD in its early stages, with seminal laboratory investigations undertaken by Prof. John Marshall FMedSci, PhD, DSc, FRCPath, FRSB, FRCOphth, and Prof. Ali Hussein at Moorfields Eye Hospital, United Kingdom. The clinical program for 2RT[®] accelerated in 2012 with the establishment of the multi-center LEAD Trial, led by Prof. Robyn Guymer FRANZCO PhD at the Centre for Eye Research Australia (CERA). Published in 2018, the 36-month results of the LEAD Trial demonstrated the potential for 2RT[®] to significantly reduce the rate of AMD progression in a specific group of intermediate AMD patients. Post hoc analyses showed that in patients who did not have coexistent reticular pseudodrusen (RPD), a fatty deposit that is associated with later stages of AMD (76% of patients enrolled), treatment with 2RT[®] resulted in a clinically meaningful 77% reduction in the rate of disease progression.

2RT[®] Positively Impacts Function of the Retina

Recently published in *Clinical & Experimental Ophthalmology*, a sub-study of the multi-center LEAD Trial conducted at CERA by Prof. Guymer and colleagues has demonstrated that 2RT[®] positively impacts the function of the retinal pigment epithelium (RPE) and the photoreceptors, key structures that support the health of the retina. Specifically, there was a statistically significant improvement in retinal function in the central region ($p=0.005$) and



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middle region ($p=0.006$) of the retina in the 2RT[®] treatment group (2RT[®] Group) at 36 months, as compared to the placebo laser treatment group (“Placebo Group”).

The sub-study enrolled 50 consecutive patients from the LEAD Trial, with 26 patients assigned to the 2RT[®] Group and 24 patients assigned to the Placebo Group. Key aspects of retinal function were objectively assessed at 6 monthly intervals over a 36-month period, or until the development of late-stage AMD, using multifocal electroretinography (mfERG). mfERG is a diagnostic technique that measures the electrical activity generated by neural and non-neuronal cells in the retina in response to a light stimulus across different areas of the retina.

The positive effect of 2RT[®] on retinal function was observed from 24 months onwards and improved further at the 36-month mark.

Commenting on the significance of the sub-study results, Director of Nova Eye Medical, Tom Spurling said: “This study demonstrates a fundamental improvement in retinal function following treatment with 2RT[®]. Importantly, it supports the stated hypothesis that 2RT[®] targets the compromised RPE to induce the orderly replacement of aged cells within the RPE, improving the overall health of the retinal environment and thereby improving its function.”

“We wish to acknowledge the pioneering work of Prof. Guymer and her colleagues at CERA. A key tenet of our success is the unique relationships we have with research institutions such as CERA. Not only does this enable us to conduct clinical investigations, but it also provides access to cutting-edge research to support the introduction of treatment innovations such as 2RT[®],” added Mr. Spurling.

The published study can be viewed at
<https://onlinelibrary.wiley.com/doi/10.1111/ceo.13823>

ABOUT 2RT

2RT[®] is a proprietary, patented laser therapy that stimulates a biological healing response in the eye to treat the intermediate stages of age-related macular degeneration (AMD) and Clinically Significant Macular Edema (CSME). Current research suggests that 2RT[®] stimulates a natural immune response of the retina, which restores natural metabolite flow and rejuvenates the retinal pigment epithelium – without damage to the overlying neurosensory retina (specifically, no damage is caused to the photoreceptors) or the underlying Bruch’s membrane. Importantly, 2RT[®] offers the potential to intervene



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earlier in the disease process and thereby eliminate or delay the risk of vision-threatening complications associated with AMD – offering a breakthrough approach to the management of AMD patients.

Ellex 2RT® Approved Indications of Use

CE MARK:

- The treatment of Clinically Significant Macular Edema (CSME); and
- In patients with early Age-related Macular Degeneration (AMD) where it can produce bilateral improvements in macular appearance and function.

US 510(k):

- The treatment of Clinically Significant Macular Edema (CSME).

ABOUT ALPHARET

Established in October 2020, AlphaRET Pty Ltd (AlphaRET) is a wholly owned subsidiary of Nova Eye Medical Limited. AlphaRET is focussed on executing the commercialization efforts for 2RT® and clearly delineates the 2RT® project from the Company's core glaucoma business. In the immediate term AlphaRET will prioritize the USA regulatory pathway for 2RT®, which includes the filing of an Investigational Device Exemption (IDE) with the US Food and Drug Administration (FDA) for a major clinical study. The aim of the study will be to obtain regulatory clearance from the FDA to treat iAMD patients with 2RT®.

ABOUT NOVA EYE MEDICAL

Nova Eye Medical Limited is a medical technology company that develops, manufactures and sells a portfolio of proprietary ophthalmic treatment technologies and devices. Used by eye surgeons in more than 100 countries globally, these technologies include iTrack™ minimally invasive glaucoma surgery (MIGS), a consumable surgical device that restores the eye's natural outflow pathway to lower pressure inside the eye and to eliminate patient reliance on anti-glaucoma medications for mild-moderate glaucoma. The Molteno3® glaucoma drainage device platform is designed to enhance surgical utility and optimize clinical outcomes for long-term IOP control in cases of severe or complex glaucoma. It also offers the benefit of a simplified and faster surgical



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profile. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by sales offices in Adelaide, Australia and Berlin, Germany, and a global network of more than 50 distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.

For additional information about Nova Eye Medical and its technologies, please visit:

www.nova-eye.com

Media enquires:

Kate Hunt

Nova Eye Medical Limited

W +61 404 080 679

khunt@nova-eye.com

Investor enquires:

Dr. Tom Duthy

Nova Eye Medical Limited

W +61 402 493 727

tduthy@nova-eye.com