
2RT[®] Clinical Update: Sub-Study Analysis of LEAD Trial Demonstrates Improved Retinal Function Following Treatment with 2RT[®]

Adelaide, Australia, 16 November 2020 – Nova Eye Medical Limited (ASX: EYE), a medical technology company committed to advanced ophthalmic treatment technologies and devices, today announces via its subsidiary AlphaRET Pty Ltd (AlphaRET) clinical results which demonstrate the ability of the Company’s proprietary 2RT[®] nano-pulse ophthalmic laser therapy to positively impact the function of the retina.

Recently published in *Clinical and Experimental Ophthalmology*, a sub-study of the 2RT[®] LEAD Trial conducted at the Centre for Eye Research Australia (CERA) by Prof. Robyn Guymer FRANZCO PhD 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, the results demonstrated a statistically significant improvement in retinal function in the central region ($p=0.005$) and 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 2RT[®] 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 with mfERG from 24 months onwards and improved further at the 36-month mark.

“The results of this sub-study demonstrate the fundamental improvement in retinal function following treatment with 2RT[®]. It also supports our 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,” commented Tom Spurling, Director of Nova Eye Medical.

“Importantly, this is the first time that a treatment has been shown to achieve an improvement in retinal function in cases of intermediate AMD.”

“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>

This release dated 16 November 2020 has been authorised for lodgement to ASX by the Board of Directors of Nova Eye Medical Limited and lodged by Simon Gray, Company Secretary.

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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 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.

ABOUT THE LEAD TRIAL

The Laser Intervention in Early AMD (LEAD) Trial, a large randomized, controlled clinical trial, demonstrated the potential for 2RT[®] to significantly reduce the rate of disease progression in a specific group of intermediate AMD patients. The study, which enrolled 292 patients, examined whether treatment with 2RT[®] could delay progression of intermediate AMD to late-stage disease. Each participant was randomly assigned to 2RT treatment (2RT Group), or a sham laser treatment (Sham Group) and received treatment and/or follow-up over three years. Despite not reaching statistical significance, when considering all patients enrolled in the trial, there was a trend to delay progression from early to late stage AMD in those treated with 2RT[®]. 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.

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 commercialisation 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 glaucoma. It also offers the benefit of a simplified and faster surgical procedure. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by 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