Positive Five-Year Post-LEAD Trial Results for 2RT®

Fremont, California, 5 March 2021 – Nova Eye Medical Limited and its subsidiary AlphaRET Pty Ltd (AlphaRET) today announce the publication of positive five-year follow-up data from a sub-study analysis of the multi-center LEAD Trial for the Company's proprietary 2RT® nano-pulse ophthalmic laser therapy.

Conducted during 2012-2018, the LEAD Trial was the first time that a laser intervention has been shown to reduce the rate of disease progression in selected patients with intermediate AMD. Specifically, post hoc analyses showed that in patients who did not have coexistent reticular pseudodrusen (RPD), a fatty deposit that is associated with the later stages of AMD (76% of patients enrolled), treatment with 2RT® resulted in a clinically meaningful 77% reduction in the rate of disease progression at 36 months following treatment.[1]

RPD is a key biomarker of retinal pigment epithelium (RPE) dysfunction and has a high association with progression to late-stage 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.

2RT® Five-Year Post-LEAD Trial Data

Recently published in *Ophthalmology Retina*, a sub-study of the multi-center LEAD Trial conducted at the Center for Eye Research Australia (CERA) by Prof. Robyn Guymer FRANZCO PhD and colleagues has demonstrated that patients without coexistent RPD who underwent treatment with 2RT® (2RT® Group) achieved a significant 68% reduction in the rate of disease progression at five years, as compared to the Sham Group (adjusted HR = 0.32; 95% CI = 0.16 to 0.65; P = 0.002). Refer to Figure 1.

The sub-study enrolled 222 patients (76%) from the LEAD Trial, with patients assigned equally to the 2RT® Group and the Sham Group respectively.

Commenting on the significance of the five-year sub-study results, Director of Nova Eye Medical, Tom Spurling said: "While the positive five-year 2RT® results in patients without RPD form part of a post-hoc analysis, the reduced rate of disease progression in these

patients, as compared to patients in the Sham Group, is significant. The ability of 2RT® to achieve such a marked reduction in the rate of progression to late-stage AMD over a five-year period is of immense benefit to patients in potentially deferring disease progression and thus maintaining their quality of life. It also supports our previously stated position that 2RT® offers a potential breakthrough approach to the treatment of AMD."

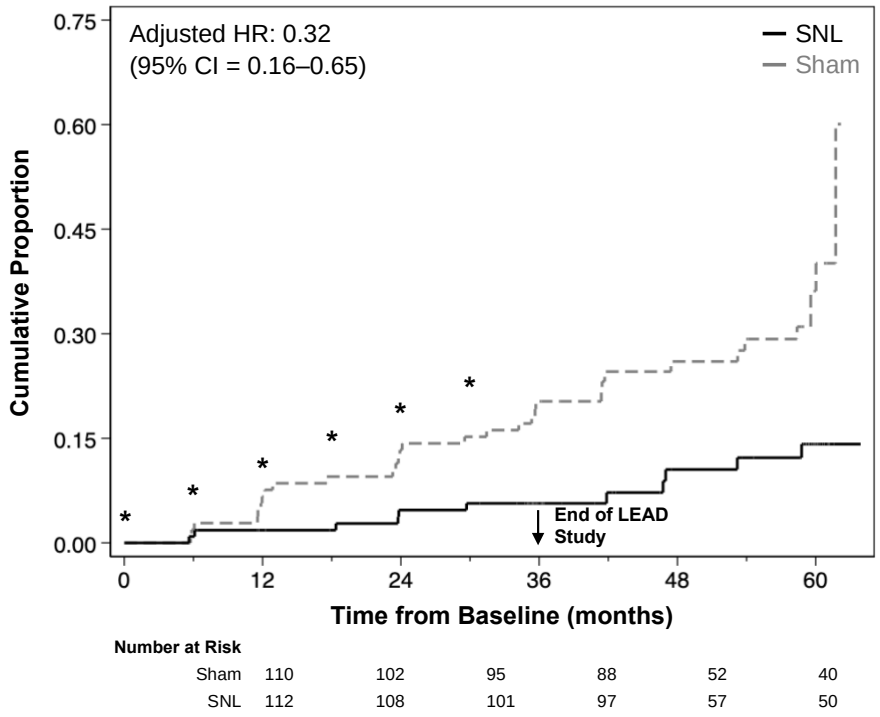
The five-year post-LEAD review also provides critical input into the Company's planned 2RT® FDA study to obtain regulatory clearance in the USA, helping to affirm the patient inclusion and exclusion criteria.

Mr. Spurling continued: "We now have a very clear picture of the patient population that we expect will benefit from our innovative 2RT® technology. This forms the basis of our pivotal study design considerations and discussions with the US FDA and the filing of an Investigational Device Exemption (IDE)."

The published study can be viewed at https://doi.org/10.1016/j.oret.2021.02.015

1. *Guymer RH, et al. Sub-Threshold Nanosecond Laser Intervention in Age-Related Macular Degeneration: The LEAD Randomized Controlled Clinical Trial. Ophthalmology. 2018 Sep 19.*

Figure 1: Rate of Disease Progression, Sham Group versus 2RT® Group (without coexistent RPD)



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.

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 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

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