

2RT® to be Featured at the 2021 Meeting of the Association for Research in Vision and Ophthalmology (ARVO)

Adelaide, Australia, 3 May 2021 – Nova Eye Medical Limited (ASX: EYE)(Nova Eye Medical or the Company), a medical technology company committed to advanced ophthalmic treatment technologies and devices, and its subsidiary AlphaRET Pty Ltd (AlphaRET), today announces that the 2RT® Laser Intervention in the Early Stages of AMD (“LEAD”) Study Group will participate in the official scientific program of the Association for Research in Vision and Ophthalmology (ARVO) meeting, 1-7 May 2021, to present the results of a 2RT® observational extension study.

The 24-month observational extension study was conducted following the LEAD Trial and examined the rate of progression to late AMD in patients from the LEAD Trial who were randomized to treatment with 2RT® (2RT® Group) as compared to patients that underwent sham treatment (Sham Group). As reported on 5 March 2021 the study showed that, at five years following the commencement of treatment with 2RT®, the rate of progression to late AMD in patients in the 2RT® Group without coexistent reticular pseudodrusen or RPD was significantly reduced, as compared to the Sham Group.

The ARVO meeting is recognized as one of the world’s top 50 medical meetings. With more than 10,000 ARVO members across the USA and globally, the annual ARVO meeting assembles the ophthalmic industry’s leading scientific researchers, clinical investigators and clinicians. With the Company expected to commence a USA Food and Drug Administration (FDA) multi-center trial to support a US 510(k) indication for 2RT® in the treatment of early AMD, which is seeking to engage preeminent retinal researchers and clinicians, it is fitting that 2RT® will be spotlighted during the 2021 meeting of the ARVO.

“We are pleased that Dr. Zhichao Wu, a member of the LEAD Study Group, which was led by Prof. Robyn Guymer, AM, MBBS, PhD, FRANZCO, FAHMS – one of the world’s most highly regarded retinal researchers and a leading authority in AMD disease management and treatment – will present data in support of the promising role of 2RT® at the 2021 meeting of the ARVO,” commented Mr. Spurling, Director of Nova Eye Medical”, commented Mr. Tom Spurling, Director of Nova Eye Medical.

“ARVO attracts the most elite retinal researchers and clinicians from across the USA. It therefore provides a very pointed platform to engage with potential study sites for the planned 2RT® FDA study.”

A copy of the abstract submitted in advance of the meeting can be located here: <https://arvo2021.arvo.org/meetings/virtual/2L6CcvxFC9D55gohY>

The 2RT® Observational Study

Following completion of the LEAD Trial, which was conducted during 2012-2018, a 24-month observational extension study was conducted on 86% (183) of patients from the LEAD Trial's two largest recruiting sites (212). Patients were assigned equally to the 2RT® Group and the Sham Group respectively. No 2RT® treatments were performed during the observational period.

At the end of the observational extension study at five years postoperative, there was a 66% reduction in the rate of disease progression in patients without coexistent RPD in the 2RT® Group, as compared to the Sham Group (adjusted HR = 0.34; 95% CI = 0.16 to 0.71; P = 0.004).

According to Prof. Guymer and colleagues, the sustained reduction in the rate of progression to late AMD in patients without RPD following treatment with 2RT® is encouraging and recommends further investigations to examine the potential value of 2RT® in the early stages of AMD.

This release dated 3 May 2021 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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Company

Tom Spurling
Director
Nova Eye Medical Limited
W +61 417 818 658
tspurling@nova-eye.com

Investors

Dr. Tom Duthy
Investor Relations & Corporate Development
Nova Eye Medical Limited
W +61 402 493 727
tduthy@nova-eye.com

Media

Kate Hunt
Head of Marketing
Nova Eye Medical Limited
W +61 404 080 679
khunt@nova-eye.com

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.

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).
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ABOUT THE LEAD TRIAL

The multi-center LEAD Trial was the first time that a laser intervention had 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. 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.

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 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