



AlphaRET

Nova Eye Medical Establishes “AlphaRET” to Fulfil the Commercial Development of 2RT®

Fremont, California, 26 October 2020 – Nova Eye Medical Limited, a medical technology company committed to advanced ophthalmic treatment technologies and devices, is pleased to report the reorganization of its 2RT® assets via the establishment of AlphaRET Pty Ltd (AlphaRET).

The establishment of AlphaRET, a wholly owned subsidiary of Nova Eye Medical Limited, will enable the Company to better concentrate its commercialization efforts for 2RT®. It will also clearly delineate the 2RT® project from the Company’s core glaucoma business.

2RT® is the Company’s proprietary nano-pulse ophthalmic laser therapy for the treatment of intermediate age-related macular degeneration (iAMD). On July 1, 2020, the Company divested its Ellex laser and ultrasound business in order to focus its efforts on the development of a portfolio of glaucoma treatment technologies. Notwithstanding the prioritization of its glaucoma business, the Company retained the proprietary 2RT® technology given its potential to meet a substantial unmet market need. AMD is the world’s leading cause of blindness in people over the age of 50, with more than 55 million patients affected by AMD annually. To date, no treatment exists for the disease in its early stages i.e. iAMD.

Commenting on the establishment of AlphaRET, Director of Nova Eye Medical, Mr. Tom Spurling said: “2RT® is a major project and offers significant upside. Despite this opportunity our core business remains firmly focused on glaucoma, underpinned by our proprietary iTrack™ and Molteno3® technologies. With the establishment of AlphaRET we will be able to better leverage the 2RT® opportunity, while continuing to foster growth of our glaucoma treatment technology pipeline under the Nova Eye Medical brand.”

2RT® is based on seminal laboratory investigations performed by world-renowned retinal expert Prof. John Marshall PhD, FRCPath, FMedDSci (Institute of Ophthalmology, University College London, UK). Prof. Marshall is actively involved in the 2RT® project and is a Board member of AlphaRET.

According to Prof. Marshall, who is a Board member of AlphaRET, 2RT® represents a huge step forward in the treatment of AMD: “2RT® is arguably the biggest advance in AMD since anti-VEGF therapy used for the late stage of the disease or Wet AMD. It is estimated that 30% of patients over 60 have some form of AMD and over 10% of this population will go on to lose some part of their vision from the late forms of this disease.



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2RT[®] is a significant breakthrough in the potential management of patients with the early stage of AMD.”

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 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).
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ABOUT THE 2RT LEAD TRIAL

The Laser Intervention in Early AMD (LEAD) 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



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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 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

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