
Nova Eye Medical Establishes AlphaRET Pty Limited to Support the Commercial Development of 2RT®

Adelaide, Australia, 26 October 2020 – Nova Eye Medical Limited (ASX: EYE)(Nova Eye Medical or the Company), a medical technology company committed to advanced ophthalmic treatment technologies and devices, today announces the establishment of AlphaRET Pty Ltd (AlphaRET™) to support the commercial development of its 2RT® asset.

2RT® is the Company's proprietary minimally invasive nano-pulse ophthalmic laser therapy which, in the 2018 Phase 2 "LEAD" clinical study, demonstrated efficacy in a subset of patients in the treatment of intermediate age-related macular degeneration (iAMD).

The establishment of AlphaRET, a wholly owned subsidiary of Nova Eye Medical Limited, will enable the Company to focus its development activities for 2RT®. It also clearly delineates the 2RT® project from the Company's core business, which is focused on glaucoma treatment technologies.

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 2RT® represents a huge step forward in the treatment of AMD, which is one of the world's leading causes of blindness. To date, no treatment exists for the disease in its early stages.

"2RT® is arguably the most significant advance in AMD since anti-VEGF therapy used for the late stage of the disease known as 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. 2RT® is a significant breakthrough in the potential management of patients with high risk earlier stage of the disease known as intermediate AMD."

Commenting on the establishment of AlphaRET, Director of Nova Eye Medical, Mr. Spurling said: "2RT® is a major project and offers the potential to meet a substantial unmet market need. 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 support the growth of our glaucoma treatment technology pipeline under the Nova Eye Medical brand."

In the immediate term AlphaRET will prioritise 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 provide statistically significant clinical evidence that 2RT delays the progression on iAMD and thereby obtain clearance from the FDA to treat patients

with iAMD.

“We are currently finalizing discussions with the FDA on the IDE and study. In parallel we will be engaging with potential commercialization partners,” added Mr. Spurling.

A summary of AlphaRET and the 2RT[®] opportunity is attached.

This release dated 26 October 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.

– ENDS –

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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. 2RT[®] has also been shown to be as effective as photocoagulation in reducing the pathology associated with CSME, but with the additional benefit of eliminating thermal damage to the neuroretina.

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 LEAD TRIAL

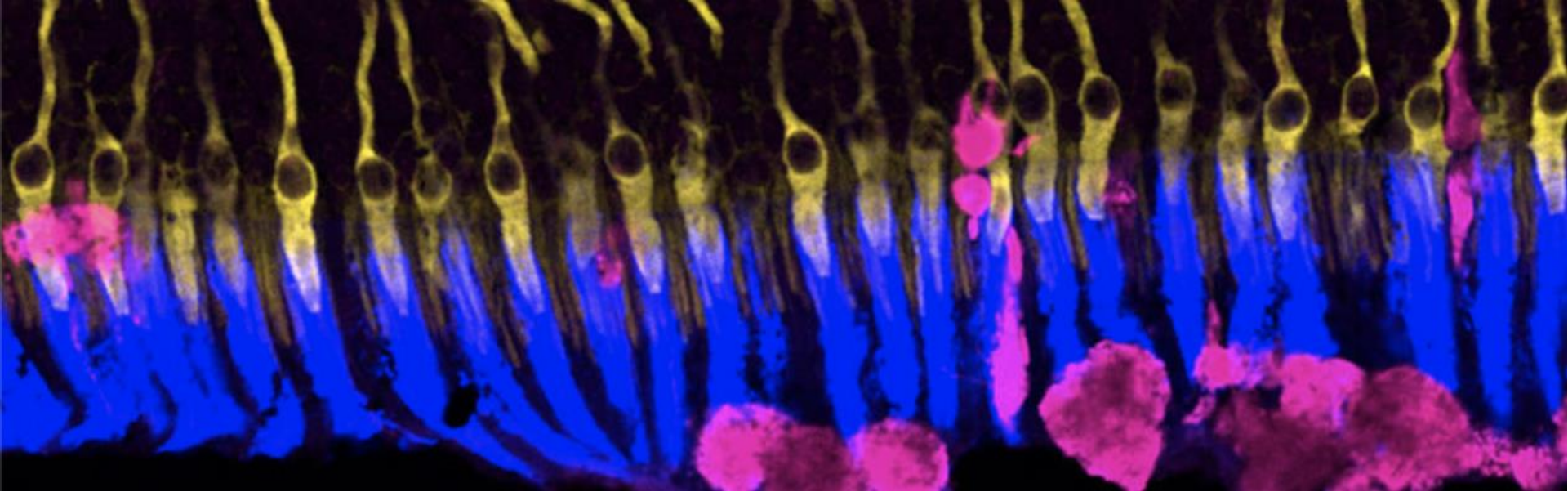
The Laser Intervention in Early AMD (LEAD) Trial, a large randomized, controlled clinical trial, demonstrated the potential for 2RT[®] to significantly reduce the rate of disease progression in a specific group of intermediate AMD patients. The study, which enrolled 292 patients, examined whether treatment 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 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



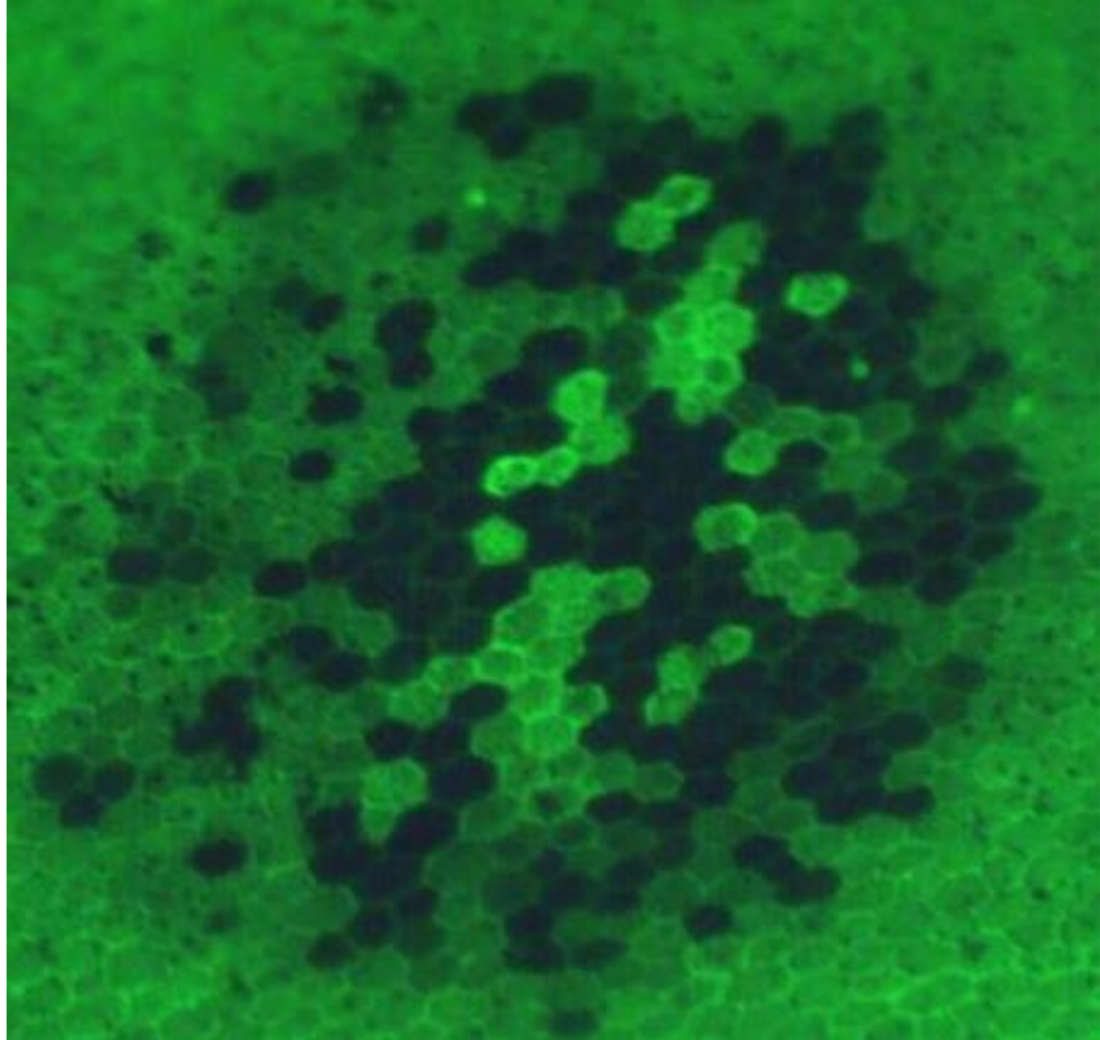
AlphaRET

AlphaRET Pty Ltd is a wholly owned subsidiary of Nova Eye Medical (ASX:EYE)

Commercial arm to facilitate development of the Company's proprietary 2RT® Project

2RT

2RT[®] is a groundbreaking proprietary therapy for patients with age-related macular degeneration (AMD) in its intermediate stage.



AGE RELATED MACULAR DEGENERATION (AMD)

- Current AMD therapy only treats the symptoms of the disease, and is only available for the late stage of the disease, using expensive pharmaceuticals delivered via invasive bi-monthly ocular injection. It is not a cure.
- The market for pharmaceuticals for treating last stage AMD is worth US\$5.25 billion per year. In Australia A\$0.4 billion is spent per year, more than any chronic disease therapy.
- AlphaRET 2RT[®] therapy is applied to AMD patients in the high risk intermediate stage of the disease and has demonstrated via a well controlled clinical study (“LEAD”) a reduction in the rate of progression to late stage disease.
- Estimated global market for 2RT[®] therapy of 55 million patients annually implies a major potential to reduce global healthcare costs.

AMD is the world's leading cause of blindness in people over the age of 50

Age is a major risk factor of AMD. AMD is most prevalent in people over 65 years old.

2RT[®] PHASE 2 CLINICAL STUDY (“LEAD”) DEMONSTRATED A REDUCTION IN THE RATE OF DISEASE PROGRESSION NOT ACHIEVED BY ANY OTHER THERAPY

2RT[®] significantly reduced rate of disease progression to late-stage AMD in patients without reticular pseudodrusen (RPD)*

For participants without RPD (76% of all participants), the rate of progression to late stage AMD was significantly reduced (adjusted HR 0.23, 95% CI 0.09–0.59; p=0.002).

* RPD is a particular deposit in the retina that can be identified with existing diagnostic imaging tools

77%

77% reduced rate of progression to late-stage AMD in 2RT[®] treated group.*

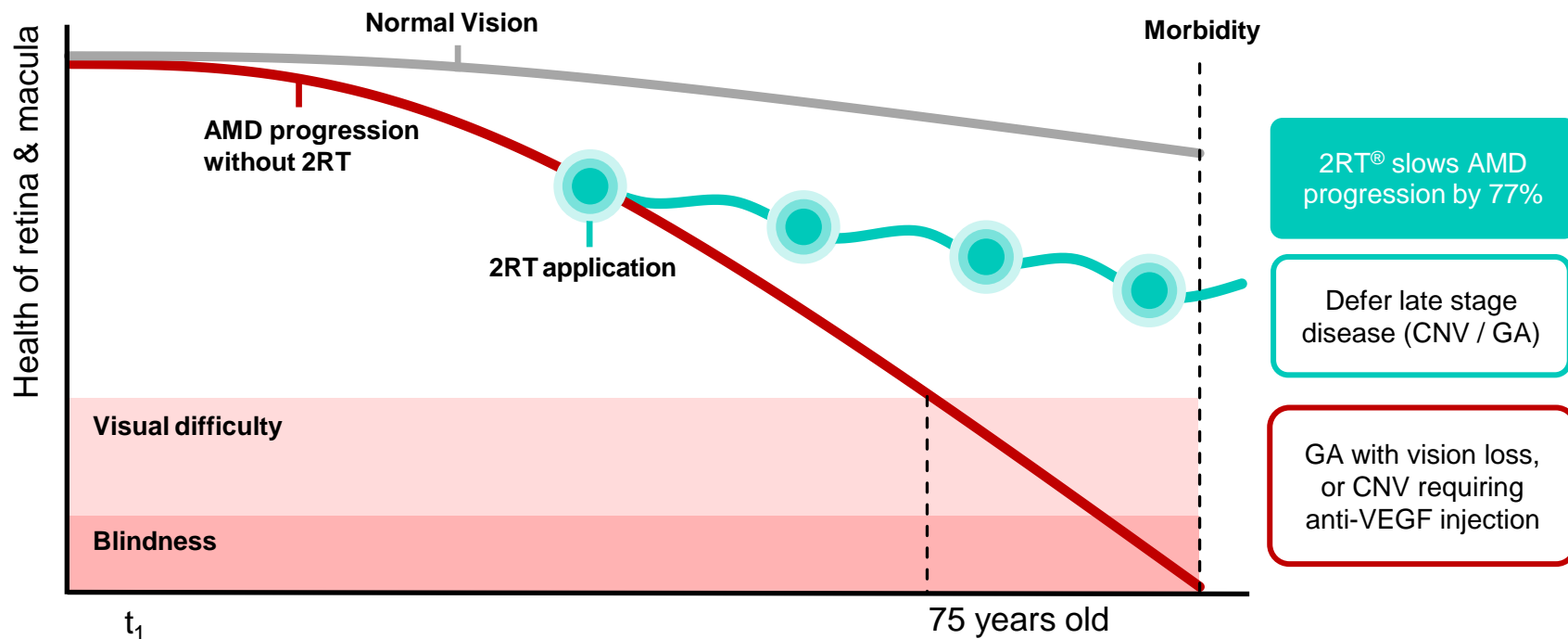
*Post hoc analysis in patients without coexistent RPD.

4x

Four-fold reduction in the rate of progression in 2RT[®] treated group compared to control, non-treated group.*

*Post hoc analysis in patients without coexistent RPD.

2RT[®] FOR PATIENTS BEFORE LATE STAGE DISEASE



2RT[®] IS READY FOR BROADER COMMERCIALISATION

Minimally invasive nano-pulse ophthalmic laser therapy for **intermediate age-related macular degeneration (iAMD)**

Seminal research by world-renowned retinal expert Prof. John Marshall PhD, FRCPath, FMedDSci **and strong intellectual property (IP) portfolio**

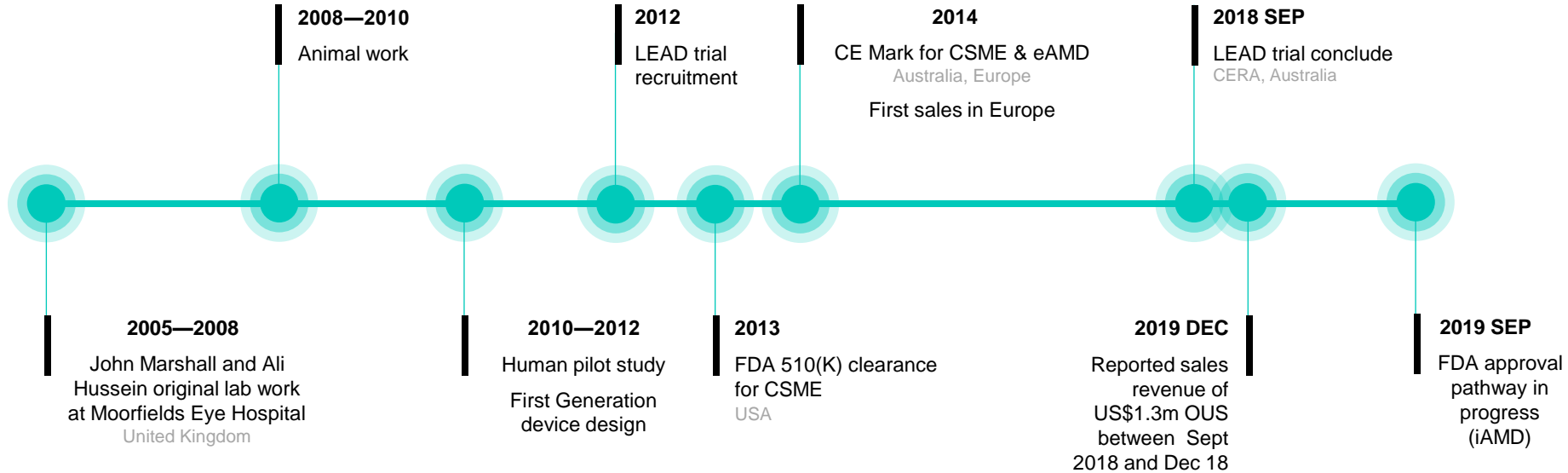
Efficacy shown in Phase 2 clinical study

Approvals in place: CE mark for sales into Europe, Australia and NZ FDA approval in place for treatment of clinically significant macular edema (not iAMD)

Sales to early adopters in Europe and Australia shows adoption of **capital equipment with procedure fee business model**

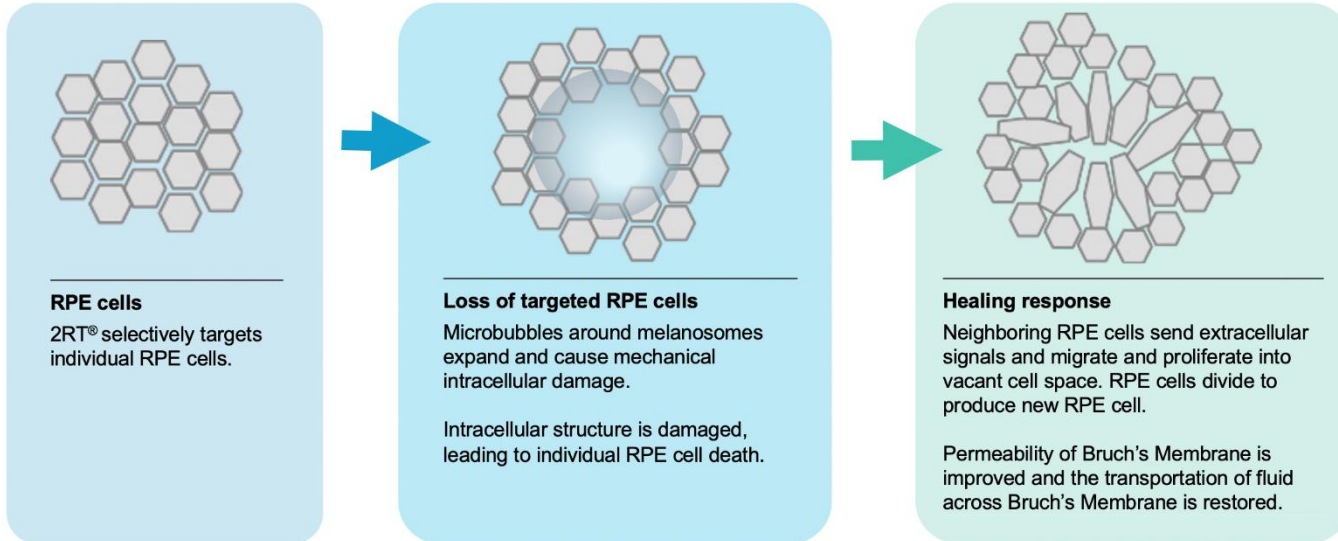
Manufacturing facilities to ISO 13485:2016 standard in place

2RT[®] HAS A STRONG DEVELOPMENT HISTORY



2RT[®] HAS A UNIQUE METHOD OF ACTION

2RT[®] stimulates a process of cell division and production of new cell growth, which improves permeability of Bruch's membrane in the inner retina and thereby restores the transport of fluid across Bruch's membrane.



“...if we can slow down the basal rate of Bruch’s membrane aging and restore function to what it was when the patient was in their teens, we should be able to significantly delay AMD onset.”

JOHN MARSHALL PhD, FRCPath FMedSci

Frost Professor of Ophthalmology, Institute of Ophthalmology, University College
London Emeritus Professor of Ophthalmology, Kings College, London

“The durability of the 2RT treatment response is compelling, particularly in the context of current treatments for the late stage of the disease i.e. wet AMD, which comprise ocular injections that need to be routinely performed every 8-10 weeks...”

PROFESSOR ANDREA CUSUMANO, MD, PhD

Researcher in Ophthalmology, Università di Roma Tor Vergata
Professor of Ophthalmology, Rheinische Friedrich-Wilhelms-Universität Bonn, Bonn, Germany
Adjunct Associate Professor, Cornell University, Weill Medical College, New York, USA

2RT[®] CAN MEET A SUBSTANTIAL UNMET NEED – iAMD

	Population with Early and Intermediate AMD ¹ (millions of people)	Remove patients with RPD, early AMD and nGA patients ² (millions of people)	Estimated population with Intermediate AMD (millions of people)
USA	13.9	-8.6	5.3
Europe	21.6	-13.4	8.2
Other wealthy nations	8.0	-5.0	3.0
Japan	5.7	-3.5	2.2
China	34.3	-21.3	13.0
LATAM and ROW	61.1	-37.9	23.2
Estimated addressable market per year			54.9 m

Late-stage Wet AMD population of 12.7m people equates to annual drug spend of \$5.3bn (Edison Research)

2RT[®] STATUS AS OF OCTOBER 2020

- LEAD (Phase 2) Study post hoc analysis showed strong results over 3 year follow up
- Expansion of 2RT[®] existing indication from FDA for use for CSME to include iAMD requires another study (Phase 3)
- Solid progress with US FDA during the 2020 year via Q-submission process
- Anticipate filing an Investigational Device Exemption (IDE) in 2H CY2020/early CY2021
- AlphaRET will partner for funding the 2RT[®] IDE study



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