
New, Additional Clinical Application for 2RT® Currently Under Investigation

Highlights

- **Investigator-initiated studies for 2RT® as a potential therapy for central serous retinopathy (CSR) commenced in Canada and Australia**
- **CSR is a disease of the retina, which typically occurs in young males aged 30-50 years and affects 10 per 100,000 males**
- **Established treatments treat symptoms but can cause retinal damage and side effects whereas 2RT® rejuvenates diseased retina cells¹.**
- **CSR represents a near term, additional market of up to US\$60 million per year**
- **Nova Eye will continue to pursue the market opportunity for age-related macular degeneration (AMD), valued at up to US\$600 million per year**

Nova Eye Medical Limited (ASX: EYE) (**Nova Eye Medical** or the **Company**), is pleased to announce that investigator-initiated studies have commenced to address the safety and effectiveness of the Company's world-first 2RT® subthreshold nano pulse laser for central serous retinopathy or CSR. If successful, these studies would underpin a new market opportunity for 2RT® in the treatment of CSR, valued at US\$60 million per year. This would be in addition to the previously stated market opportunity for 2RT® in the treatment of AMD, which is valued at US\$600 million per year.

The unique method of action of 2RT® that stimulates rejuvenation of the retinal pigment epithelium (RPE)^{1,4}, makes therapy with 2RT® potentially better for patients with CSR.

Central serous retinopathy is the fourth most common retinal disease after age-related macular degeneration, diabetic eye disease and branch retinal vein occlusion. It occurs when fluid builds up under the retina, resulting in sudden central vision loss or distortion. According to the American Academy of Ophthalmology (AAO), males in their 30s to 50s are more likely to develop CSR. Approximately 10 per 100,000 males are impacted by CSR². Chronic and untreated CSR has been shown to result in progressive damage to the retina.

According to the published literature³, current treatment options for CSR are primarily limited to thermal laser therapy and photodynamic therapy. Despite offering good efficacy, these treatment options carry a high-risk profile: thermal lasers have been shown to cause permanent damage to the retinal pigment epithelium (RPE)^{4,5}, an important layer of cells in the retina, while photodynamic therapy may have unfavourable side effects³.

The two investigator-initiated studies to assess the clinical utility of 2RT[®] in the treatment of CSR are currently underway in Toronto, Canada and Melbourne, Australia. The study in Australia is being supported with equipment supplied by AlphaRET Pty Ltd, the wholly owned subsidiary of Nova Eye Medical responsible for commercialising 2RT.

The first study, being conducted by Shaheer Aboobaker, MD and David Chow, MD, Toronto Retinal Institute, will investigate the role of 2RT[®] for acute CSR. To date, 25 patients have been recruited in the study.

The second study, being conducted by Mali Okado MBBS, BMedSci, MMed, Centre for Eye Research Australia (CERA) and Professor Wilson Heriot MBBS, FRANZCO, Retinology Institute Glen Iris, Victoria, Australia, will investigate the role of 2RT[®] for acute chronic CSR. To date, 10 patients have been recruited in the study (ClinicalTrials.gov Identifier: NCT05570591).

According to Professor Heriot, the ability of 2RT[®] to improve RPE function may make it ideally suited to the treatment of CSR: “2RT[®] has a unique method of action that does not cause damage to the retina. In young CSR patients this is very important. I think that 2RT[®] could have a major role to play in treating this disease.”

Commenting on the interest in the study, Dr. Okada stated: “Our study has garnered a lot of interest as often there are no easily accessible therapies for this disease. These patients are often busy and the prospect of a quick in-office treatment with 2RT[®] is appealing – particularly compared to photodynamic therapy, which requires intravenous infusion of a photosensitising agent into the bloodstream, followed by laser-based activation, in a hospital or OR-based setting.”

The studies will provide feedback on safety and efficacy and, if successful, could expand the clinical application of 2RT[®] to include the treatment of CSR, as well as other retinal diseases caused by RPE dysfunction. The study results are expected to be available in approximately 12 months’ time.

This release dated 25 January 2023 has been authorised for lodgement to ASX by the Board of Directors of Nova Eye Medical Limited and lodged by Simon Gray, Company Secretary.

Citations

1. Jobling, A.I., et al., Nanosecond laser therapy reverses pathologic and molecular changes in age-related macular degeneration without retinal damage. FASEB J, 2015. 29,696-710
2. Central serous chorioretinopathy: a review of epidemiology and pathophysiology, Clin Exp Ophthalmol, 2013 Mar;41(2):201-14

3. https://eyewiki.aao.org/Central_Serous_Chorioretinopathy
4. Wood, JPM., et al., Physiological response of the retinal pigmented epithelium to 3-ns pulse laser application, in vitro and in vivo. Clin Exp Ophthalmol. 2021 Jul;49(5):454-469
5. Cohn, AC., et al., Subthreshold Nano-Second Laser Treatment and Age-Related Macular Degeneration. J Clin Med. 2021 Jan 28;10(3):484

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ABOUT CENTRAL SEROUS RETINOPATHY

Central serous retinopathy or CSR is the fourth most common retinal disease after age-related macular degeneration, diabetic retinopathy and branch retinal vein occlusion. It is a disease of the choroid with secondary dysfunction of the retinal pigment epithelium. It typically occurs in males in their 30s to 50s who exhibit acute or sub-acute central vision loss or distortion. Annual Incidence 9.9 per 100,000 in men and 1.7 per 100,000 women.

ABOUT ALPHARET PTY LTD

AlphaRET Pty Ltd (AlphaRET) is a wholly owned subsidiary of Nova Eye Medical Limited. AlphaRET is focussed on executing the commercialization efforts for 2RT®.

For additional information about AlphaRET and 2RT®, please visit: www.alpha-RET.com

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 advanced and complex 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
