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## **Nova Eye Medical Files IDE Application with the FDA to Commence a Pivotal Study in the US Evaluating 2RT®**

**Adelaide, Australia, 5 July 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 the filing of an Investigational Device Exemption (IDE) application with the US Food and Drug Administration (FDA) to commence a pivotal study for the Company's proprietary, patented 2RT® laser for intermediate age-related macular degeneration (iAMD).

The lodgement of the IDE application is a key milestone required to commence a pivotal study in the USA to demonstrate the safety and effectiveness of the 2RT® treatment for iAMD. The next milestone will be the receipt of feedback from the FDA on the application.

Mr. Tom Spurling, Director of Nova Eye Medical, commented: "2RT® is an important technology and filing the IDE was a significant undertaking. An investment of approximately \$1 million over more than 12 months has been made to achieve this milestone. Once it is approved as a treatment, we estimate that, in the major developed markets, 25 - 50 million people per year could benefit from 2RT®."

***This release dated 5 July 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.***

**– ENDS –**

**Company**

Tom Spurling  
Director  
Nova Eye Medical Limited  
W +61 417 818 658  
[tspurling@nova-eye.com](mailto: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](mailto:tduthy@nova-eye.com)

**Media**

Kate Hunt  
Head of Marketing  
Nova Eye Medical Limited  
W +61 404 080 679  
[khunt@nova-eye.com](mailto:khunt@nova-eye.com)

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**ABOUT 2RT**2RT® 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 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 pivotal clinical study. The aim of the pivotal study will be to obtain regulatory clearance from the FDA to treat iAMD patients with 2RT®.

For additional information about AlphaRET, please visit: [www.alpha-ret.com](http://www.alpha-ret.com)

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**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](http://www.nova-eye.com)