
Nova Eye Medical Launches New Clinical Trial to Assess Efficacy and Safety of iTrack™ in the Treatment of Mild to Moderate Glaucoma

Adelaide, Australia, 2 March 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, today announces the commencement of a prospective, randomized, single-masked trial across eight surgery centres in the USA to assess the efficacy and safety outcomes of the ab-interno canaloplasty procedure using the Company's iTrack™ canaloplasty microcatheter, as compared to the OMNI® device (Sight Sciences) in the treatment of mild to moderate glaucoma.

Titled "MAGIC" – Multi-center Ab-interno Glaucoma study Investigating Canaloplasty – the multi-centre trial will be performed over a 12-month period and will enrol 160 patients with mild to moderate, uncontrolled primary open-angle glaucoma (POAG) on 1-4 medications. Patients will be randomized to treatment with the iTrack™ canaloplasty microcatheter and the OMNI® device respectively. The reduction in mean intraocular pressure (IOP) and mean number of anti-glaucoma medications will be assessed, as well as surgical and postoperative complications.

The formal trial design is highlighted in Appendix 1.

According to Shamil Patel, MD, Principal Investigator of the MAGIC Trial and Senior Ophthalmologist at Eye Physicians & Surgeons of Arizona, the ability to deploy ab-interno canaloplasty as a standalone procedure, and in combination with cataract surgery, supports its versatility in the glaucoma treatment algorithm.

The unique mechanism of action of ab-interno canaloplasty, which acts to reduce outflow resistance in all parts of the natural drainage system, further supports its role in the glaucoma treatment armamentarium.

"Ab-interno canaloplasty is akin to cardiac angioplasty for the eye. Comprising 360° catheterization of Schlemm's canal followed by the delivery of viscoelastic into the canal via a process referred to as viscodilation, the multimodal mechanism of ab-interno canaloplasty addresses multiple points of blockage in the conventional outflow pathway. This makes it an effective treatment in the majority of my mild-moderate open-angle glaucoma patients, with most patients achieving post-operative pressures in the low teens," said Dr. Patel.

"Despite this, ab-interno canaloplasty has suffered from a misconception that, due to its implant-free and tissue-sparing approach, it does not deliver the same degree of efficacy as other MIGS

procedures.”

Ab-interno canaloplasty is a tissue-sparing, implant-free procedure that acts to re-establish the function of the eye’s natural drainage system to effectively reduce IOP and the medication burden, while also preserving the viability of future treatment options. As a result, an increasing number of surgeons are turning to ab-interno canaloplasty to manage their mild-moderate glaucoma patients. In contrast, many other MIGS procedures bypass the natural drainage system or remove tissue.

“Together with doctors Mahmoud A. Khaimi, Mark J. Gallardo, George Reiss, Robert Noecker, Inder P. Singh, Justin Spaulding, Billy Pan, Dan Tran and David Lubeck (Medical Monitor), I look forward to demonstrating the clinical utility of ab-interno canaloplasty. I also look forward to evaluating whether the device type impacts this utility,” added Dr. Patel.

Tom Spurling, Director of Nova Eye Medical said: “We are pleased to have commenced this important study of iTrack™, to provide more clinical evidence that iTrack™ offers clinicians the best available canaloplasty device option when treating their mild to moderate glaucoma patients. This study builds on the existing body of clinical evidence that validates iTrack as an effective, tissue sparing, implant-free MIGS procedure”

The MAGIC Trial is expected to reinforce the clinical utility of ab-interno canaloplasty in the treatment of mild-moderate glaucoma patients. Details of the trial can be viewed at [clinicaltrials.gov](https://clinicaltrials.gov/NCT04769453), NCT04769453.

** OMNI is a registered trademark of Sight Sciences, Inc.*

This release dated 2 March 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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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

Appendix 1 – MAGIC Clinical Trial Summary

Title	M ulti-center A b-interno G laucoma study I nvestigating C analoplasty (MAGIC)
Investigated devices	iTrack surgical system; OMNI surgical system; Healon GV/ Healon Pro
Study Design	Prospective, multi-centre, randomised, single-masked 2x2 factorial clinical trial with follow-up through 12 months
Randomisation	Participants will be randomised 1:1:1:1 into one of the four groups (1) OMNI + Healon GV Pro; (2) OMNI + Healon Pro; (3) iTrack + Healon GV Pro; (4) iTrack + Healon Pro
Study Objectives(s)	To demonstrate that circumferential viscodilation using iTrack results in greater reduction in IOP and medication use at 12 months compared to OMNI, and to investigate whether there are clinically meaningful differences between the use of Healon GV vs Healon GV Pro in reduction of IOP and medication use at 12 months
Primary Endpoints	Change in mean Intraocular Pressure (IOP) and Medication use at 12 months compared to baseline
Secondary Endpoints	Complications/adverse events associated with iTrack and OMNI, Healon Pro and Healon GV Pro respectively, Visual acuity at 12 months
Number of Subjects	Up to 78 eyes per arm of 156 qualified subjects, across 8 investigational sites in the USA
Disease	Confirmed diagnosis of moderate open angle glaucoma

Further details of the study can be found at clinicaltrials.gov, identifier: NCT04769453