iTrack™ MIGS Procedure Under Assessment for Public Funding via the Australian Government's Medical Benefit Scheme

Fremont, California, 18 February 2021 – Nova Eye Medical Limited, a medical technology company committed to advanced ophthalmic treatment technologies and devices, is pleased to report that an application to secure public funding for the Company's patented iTrack™ ab-interno canaloplasty as a standalone minimally invasive glaucoma surgery (MIGS) procedure via the Australian government's Medical Benefits Scheme has received a positive boost, formally progressing to the third and final stage of the assessment process.

The application to include iTrack™ on the Prostheses List is currently under review by the Medicare Services Advisory Committee (MSAC), an independent body appointed by the Australian Government to assess the allocation of public funding for medical devices and procedures covered by the Medicare Benefits Schedule.

The Company's application is seeking to amend the existing standalone MIGS Medicare Item Number, #42504, to include its iTrack™ microcatheter technology, and has garnered support from the Australian and New Zealand Glaucoma Society (ANZGS), Glaucoma Australia and The Australian Society of Ophthalmologists (ASO).

iTrack™ has been registered in Australia by the Therapeutic Goods Administration (TGA) since June 2015 and is currently approved for use in five major teaching hospitals in New South Wales, Western Australia and Victoria.

The Company is confident that the unique mechanism of the iTrack™ procedure, which acts to restore the function of the eye's drainage system rather than to bypass it or change it, combined with its excellent safety profile, will enable iTrack™ to make a significant, positive impact on the glaucoma treatment landscape in Australia.

"The majority of MIGS procedures, including trabecular micro-bypass stent surgery, are focal in their approach. That is, they attempt to remove or bypass a particular point of blockage. In contrast, ab-interno canaloplasty aims to remove all points of

blockage in the conventional outflow system – and does so without damaging or removing tissue, and without the use of a permanent implant," commented Tom Spurling, Director of Nova Eye Medical Limited.

"iTrack is routinely deployed via an ab-interno approach across the USA and Europe in the treatment of mild-moderate glaucoma, and there is a growing body of clinical evidence attesting to its clinical efficacy and safety profile, both as a standalone MIGS procedure and in combination with cataract surgery."

"Surgeons in the USA have readily adopted the procedure. This is due, in part, to the fact that it is medically reimbursed with a Category 1 CPT (Current Procedural Terminology) Code," added Mr. Spurling.

Another reason behind the increased adoption of iTrack™ in the USA and Europe is the tissue-sparing, implant-free approach of the procedure, which preserves both the conjunctiva and the angle for future treatments. It has also been shown to preserve the corneal endothelium.

Interim 12-month prospective data to be presented at the 2021 meeting of the American Society of Cataract and Refractive Surgeons meeting by US surgeons David Lubeck, MD and Robert Noecker, MD has demonstrated minimal endothelial cell loss (ECL) following iTrack™ ab-interno canaloplasty (performed in conjunction with cataract surgery), with mean ECL -4.8%[1]. The pivotal FDA trials for iStent inject (Glaukos)[2] and Hydrus (Ivantis)[3] recorded mean ECL at 24 months of -13.1% (control group = 12.3%) and -14.0% (control group = 10.0%) respectively.

The final assessment of the Company's application is being completed by a contracted health technology assessment agency, assigned by the MSAC secretariat and will be considered by the Evaluation Sub-Committee (ESC) in the second half of 2021, at which point a decision will be made regarding whether to include iTrack™ in the Medicare Item Number #42504.

1. *Lubeck DM, Singh IP, Noecker RJ. Evaluation of Endothelial Cell Density and Loss Following iTrack Ab-Interno Canal Based Surgery. ASCRS 2020 (Paper Presentation).*
2. *Samuelson, T et al, Prospective, Randomized, Controlled Pivotal Trial of an Ab Interno Implanted Trabecular Micro-Bypass in Primary Open-Angle Glaucoma and Cataract, Ophthalmology June 2019, pages 811-821 2.*
3. *Samuelson, T et al, A Schlemm Canal Microstent for Intraocular Pressure Reduction in Primary Open-Angle Glaucoma and Cataract, Ophthalmology, Jan 2019, pages 29-37*

ABOUT AB-INTERNO CANALOPLASTY

Canaloplasty was first introduced in 2005 as an alternative to trabeculectomy in the treatment of severe glaucoma, performed via an ab-externo approach. Over time, refinement of the procedure by physicians has seen canaloplasty performed via an ab-interno approach to preserve the conjunctiva and sclera. Today, canaloplasty is commonly deployed in clinical practice via an ab-interno approach in the treatment of mild and moderate glaucoma. For additional information about iTrack™ ab-interno canaloplasty, please visit: www.glaucoma-iTrack.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. 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

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