Prospective Multi-Center Trial to Compare Efficacy and Safety Outcomes of Ab-Interno Canaloplasty for Glaucoma

Fremont, California, 2 March 2021 – Nova Eye Medical Limited, a medical technology company committed to advanced ophthalmic treatment technologies and devices, is pleased to report that eight surgery centers across the USA have commenced a prospective, multi-center, randomized trial to assess the efficacy and safety outcomes of ab-interno canaloplasty.

Titled "MAGIC" – **M**ulti-center **A**b-interno **G**laucoma study **I**nvestigating **C**analoplasty (NCT04769453) – the single-masked 2x2 factorial trial will assess a number of factors that impact the clinical outcomes of ab-interno canaloplasty, including a comparison of the Company's iTrack™ Canaloplasty Microcatheter with the OMNI® Surgical System (Sight Sciences). The clinical impact of the type of ophthalmic viscosurgical device (OVD) used during the procedure, and the volume of OVD delivered, will also be assessed.

Ab-interno canaloplasty will be performed as a standalone procedure during the MAGIC Trial, to eliminate the confounding effect of cataract surgery, which has been shown to lower IOP in some glaucoma patients.

The trial will be performed over a 12-month period and will enrol up to 160 patients with mild to moderate, uncontrolled primary open-angle glaucoma (POAG) on 1-4 medications. Patients will be randomized to the iTrack™ and OMNI® treatment groups respectively. Primary endpoints will include reduction in mean IOP and mean number of anti-glaucoma medications. Secondary endpoints will include surgical and postoperative complications.

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 reduces outflow resistance in all parts of the natural drainage system – the trabecular meshwork (the spongy tissue located near the clear part of the eye known as the cornea), Schlemm's canal (a circular channel adjacent the trabecular meshwork) and the collector channels – 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 OVD into the canal via a process of 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.

“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.”

In the USA, both the iTrack™ Canaloplasty Microcatheter and the OMNI® Surgical System are used by glaucoma surgeons in the treatment of mild-moderate glaucoma patients. The iTrack™ Canaloplasty Microcatheter has been cleared by the FDA (510k) for the indication of fluid infusion and aspiration during surgery, and for catheterization and viscodilation of Schlemm’s canal to reduce intraocular pressure in adult patients with open angle glaucoma. The OMNI® Surgical System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon® Pro or Healon GV® Pro from Johnson & Johnson Vision, Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery. It has been cleared by the FDA (510k) to cut trabecular meshwork tissue during trabeculotomy procedures. To permit a true head-to-head comparison of the clinical outcomes of ab-interno canaloplasty, the MAGIC Trial protocol will entail catheterization and viscodilation only.

“Along with the other trial investigators, I am of the strong opinion that the removal of tissue should be avoided in the treatment of mild-moderate glaucoma patients, where possible. We know that glaucoma is a multifactorial disease. I want to preserve the trabecular meshwork tissue to leave us with the option to treat the patient’s drainage system again, depending on how their disease progresses. The tissue-sparing aspect of ab-interno canaloplasty does not limit us from future surgical options that rely on the presence of the trabecular meshwork,” added Dr. Patel.

The role of OVD – a hyaluronic acid-based gel-like substance, which is delivered into Schlemm's canal during the procedure – will also be evaluated during the MAGIC Trial. Specifically, the clinical impact of the of type and volume of OVD delivered will be assessed.

"I take advantage of the capability to titrate the amount of OVD delivered, based on the patency of Schlemm's canal, with the iTrack™ Canaloplasty Microcatheter. The more occluded the canal, for example, the more OVD that is required to break adhesions and push out herniations of the trabecular meshwork. The MAGIC Trial will elucidate whether adjustments to the volume of OVD delivery translate to improved clinical outcomes for our patients," said Dr. Patel.

"We will also run a sub-analysis to assess whether there is a correlation between OVD type and clinical outcomes, with patients randomized to receive either Healon GV® Pro or Healon® Pro. Not only will this help to further our understanding of how viscodilation acts to reverse the pathological changes in glaucomatous eyes to improve outflow facility, but it will also enable us to evolve the treatment protocol for ab-interno canaloplasty accordingly."

According to Joe Bankovich, President of Nova Eye Medical, the Company's iTrack™ Canaloplasty Microcatheter is the only device designed specifically for canaloplasty. It is also the only device cleared by the FDA (510k) for viscodilation of Schlemm's canal in the treatment of glaucoma, first introduced back in 2004 following seminal clinical investigations by Prof. Robert Stegmann and Dr. Murray Johnstone.

"It is easy to overlook the masterful design of the iTrack™ canaloplasty microcatheter. At just 250 microns it is equivalent to several strands of hair and yet it comprises an infusion pathway for the delivery of OVD, a fiber optic and a guide wire. Every element has been meticulously designed in order to enable 360° catheterization of the canal and to achieve pressurized viscodilation – both of which are fundamental to the clinical success of canaloplasty," said Mr. Bankovich.

"Without sufficient pressure the OVD may pass through the patent collector channels without impacting on the areas of outflow resistance."

"We know from lab testing that our iTrack™ Canaloplasty Microcatheter delivers more OVD into Schlemm's canal than any other device. We also know that it does

so via a pressurized mechanism, designed to pop open herniations of the collector channels. For these reasons, we consider iTrack™ to be the superior canaloplasty device," concluded Mr. Bankovich.

"iTrack™ also offers additional benefits from a safety standpoint, featuring an illuminated fiber optic top. This enables the surgeon to monitor its progress through every treatment step and thus helps to safeguard against misdirection into the suprachoroidal space or the collector channels, which can cause patient discomfort."

The MAGIC Trial is expected to reinforce the clinical utility of ab-interno canaloplasty in the treatment of mild-moderate glaucoma patients. The Company anticipates publication of the completed 12-month results in the second half of 2022.

Details of the MAGIC Trial can be viewed at clinicaltrials.gov, NCT04769453.

1, Gallardo MJ, Supnet RA, Ahmed IIK. Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach. Clinical Ophthalmology. Vol 12. August 2018.

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. Unlike other minimally invasive glaucoma surgery (MIGS) procedures, which bypass the natural drainage system or remove tissue, ab-interno canaloplasty is a tissue-sparing, implant-free procedure that acts to re-establish the function of the eye's natural drainage system – achieving an average reduction in IOP of 30%[1] 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.

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 or complex glaucoma. It also offers the benefit of a simplified and faster surgical profile. 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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