Nova Eye Medical Launches Multi-Center 'CATALYST' Study in Europe to Investigate Canaloplasty with the new *iTrack™ Advance*

Adelaide, Australia,11 August 2022 – 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 enrolment of the first patient in the prospective, randomized, multicenter CATALYST Study.

To be conducted across five sites in Germany, CATALYST will assess the effectiveness, safety and quality of life (QoL) outcomes of the canaloplasty procedure using the Company's new *iTrack™ Advance* device. The multicenter study will enrol up to 80 patients with mild to moderate, uncontrolled open-angle glaucoma on 1-4 medications. Patients will be randomized to treatment with canaloplasty performed in combination with cataract surgery ("Canaloplasty Group") compared to cataract surgery-only ("Control Group").

Key assessment outcomes will include reduction in mean intraocular pressure (IOP) and mean number of glaucoma medications, surgical and postoperative complications, endothelial cell count and QoL utilizing a patient reported outcome measure.

The formal study design is highlighted in Appendix 1.

Prof. Dr. med. Norbert Koerber, FEBO, Augencentrum Köln-Porz, Köln, Germany, will assume the role of Primary Investigator for the CATALYST Study.

An internationally renowned glaucoma surgeon and one of the pioneers of the canaloplasty procedure, Prof. Koerber has been performing canaloplasty for nearly two decades.

"I have been a proponent of traditional canaloplasty for many years and continue to offer it to my severe glaucoma patients to push back the need for trabeculotomy or tube shunt surgery. More recently I have adopted canaloplasty via an ab-interno surgical technique in patients with mild-moderate glaucoma. Many of these patients experience unwanted side effects from glaucoma medications or fail to administer their medications as prescribed. For these patients, modern-day canaloplasty, performed via an ab-interno

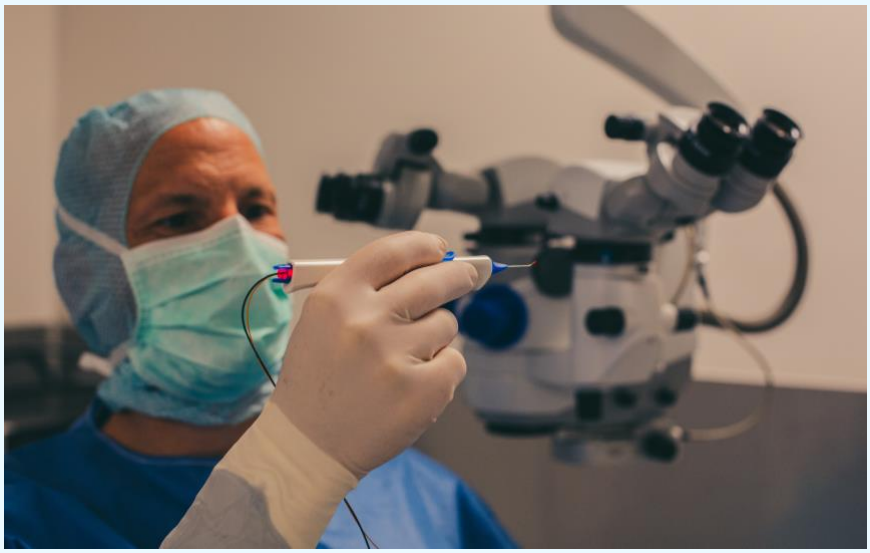
surgical technique, offers an early surgical intervention that acts in a similar way to angioplasty to flush out the eye's drainage channel and lower IOP, eliminating or reducing the need for medications."

The *iTrack™ Advance* is cleared for canaloplasty both with and without cataract surgery. All canaloplasty procedures in the CATALYST Study will be performed in combination with cataract surgery, however.

"Along with my co-investigator Simon Ondrejka, we have performed more than 20 procedures with the new *iTrack™ Advance* device. The major advantage of this new device for the surgeon is that it allows canaloplasty to be a truly single-handed surgical procedure. The handpiece features a custom-designed cannula which enables the surgeon to create an opening in the meshwork, before using the injector on the handpiece to guide the microcatheter easily into the canal – all using only one hand. We believe this progress in the device design is a crucial step in encouraging more cataract surgeons to perform ab-interno canaloplasty in combination with cataract surgery. The combined cataract surgery-canaloplasty procedure offers a number of benefits to patients," commented Prof. Dr. med. Koerber.

Tom Spurling, Managing Director of Nova Eye Medical, said: "We are pleased to have commenced this important European study with our latest generation canaloplasty device *iTrack™ Advance*. We are also proud and humbled that, just over 10 years after participating in the 2011 pivotal multi-center study which underpinned market clearance of the traditional (ab-externo) canaloplasty procedure*, Professor Koerber will join his German colleagues to further bolster the clinical evidence in support of modern-day canaloplasty, or ab-interno canaloplasty."

The CATALYST Study is expected to reinforce the clinical utility of canaloplasty in the treatment of mild to moderate glaucoma patients.



Pictured: Dr. Ondrejka with the new iTrack™ Advance device, which features a proprietary illuminated tip that enables the surgeon to visualize the microcatheter through every procedural step.

Pictured: Dr. Ondrejka (right) performs a canaloplasty procedure with the new iTrack™ Advance device. During the withdrawal of the microcatheter, the scrub nurse (left) titrates the ViscoInjector™ viscoelastic delivery device to deliver a custom volume of OVD, based on the patient's pathology.

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 the iTrack™ portfolio of canaloplasty devices for the treatment of glaucoma. The Company also manufactures and sells the proprietary Molteno3® glaucoma drainage device for the treatment of severe or complex 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

ABOUT CANALOPLASTY

First introduced in 2008, canaloplasty is a surgical treatment for glaucoma that targets the main sites of outflow resistance in the conventional outflow pathway: the trabecular meshwork, Schlemm's canal, and the distal collector channels. Based on the same principles as angioplasty, a flexible microcatheter is cannulated 360 degrees around Schlemm's canal during the procedure to manually break and remove blockages. Next, viscoelastic fluid is injected into Schlemm's canal as the microcatheter is withdrawn to dilate the distal outflow system and to improve the function of the trabecular meshwork.

Canaloplasty is typically performed using either of the following two surgical techniques.

- Performed via an ab-interno surgical technique, canaloplasty is a highly effective treatment option for cases of mild-moderate glaucoma. It typically reduces intraocular pressure (IOP) to the low teens. It has also been observed to reduce patient dependence on medications. Importantly, the ab-interno surgical

technique is an implant-free, tissue-sparing procedure that preserves future treatment options.

- Performed via an ab-externo surgical technique, canaloplasty is a highly effective treatment option for patients with severe glaucoma that overcomes the risks and discomfort associated with traditional glaucoma surgery. With over 100,000 procedures performed to date, clinical studies show that canaloplasty has an excellent safety profile, with minimal post-operative follow-up, fast recovery time, and infrequent intra-operative and postoperative complications.

ABOUT THE iTRACK™ PORTFOLIO

Nova Eye Medical (formerly iScience Interventional) pioneered the canaloplasty market with the launch of the world's first canaloplasty device, *iTrack*™, in 2008. Since then, more than 100,000 canaloplasty procedures have been performed with the *iTrack*™ device, cementing its role in the treatment of glaucoma both as a standalone procedure and in combination with cataract surgery. Launched in 2022, the *iTrack*™ *Advance* leverages the proprietary features of the original *iTrack*™ device but incorporates a new handheld injector and cannula, which improves the overall surgical efficiency of the canaloplasty procedure.

For additional information about *iTrack*™ *Advance*, including safety information, please visit: https://itrack-advance.com/

iTrack™ Advance has a CE Mark (Conformité Européenne) for the treatment of open-angle glaucoma and is currently available in selected markets in Europe and the Asia Pacific. iTrack™ Advance is not available for use or sale in the USA. The iTrack™ Advance is indicated for 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.

iTrack™ has a CE Mark (Conformité Européenne) and US Food and Drug Administration (FDA) 510(k) # K080067 for the treatment of open-angle glaucoma. The iTrack™ canaloplasty microcatheter has been cleared 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 iTrack™ canaloplasty microcatheter is currently not 510(k) cleared for use with the ab-interno technique in the United States.

Appendix 1: CATALYST Clinical Trial Summary

TITLE	Cataract Surgery in Conjunction with Ab-interno Canaloplasty Compared to Cataract Surgery Only in Patients with Mild to Moderate Primary Open-Angle Glaucoma ("CATALYST")
INVESTIGATED DEVICES	iTrack™ Advance (Nova Eye Medical)
STUDY DESIGN	Prospective, multicenter, randomized clinical study with follow-up through 12 months
PATIENT POPULATION	Up to 80 qualified subjects across two treatment groups: 1. Canaloplasty Group: canaloplasty in combination with cataract surgery (iTrack™ Advance) 2. Control Group: cataract surgery-only Subjects will be randomized in a 2:1 ratio, with two (2) patients enrolled in the Canaloplasty Group for one (1) patient enrolled in the Control Group.
DISEASE	Mild to moderate open-angle glaucoma
STUDY OBJECTIVE(S)	• To demonstrate the reduction in mean IOP and mean number of medications in mild-moderate OAG patients at 12 months following (ab-interno surgical technique) canaloplasty using the *iTrack™ Advance* device in combination with cataract surgery, as compared to cataract surgery only. • To demonstrate the mean endothelial cell loss at 12 months associated with (ab-interno surgical technique) canaloplasty using the *iTrack™ Advance* device in combination with cataract surgery, as compared to cataract surgery only. • To investigate quality of life (QoL) and patient satisfaction with treatment following (ab-interno surgical technique) canaloplasty in combination with cataract surgery, as compared to cataract surgery only.

PRIMARY ENDPOINTS	• Change in mean IOP and medication use at 12 months.
SECONDARY ENDPOINTS	• Complications/adverse events comparing (ab-interno surgical technique) canaloplasty in combination with cataract surgery, as compared to cataract surgery only. • Visual acuity, endothelial cell count and QoL outcomes at 12 months compared to baseline.
STUDY SITES	• Dr. med. Simon Ondrejka (Augencentrum Köln-Porz, Köln) • Prof. Dr. med. Markus Kohlhaas, FEBO (St. Johannes Hospital Dortmund, Dortmund) • Prof. Dr. med. Anselm G.M. Jünemann, FEBO (Universitätsmedizin Rostock, Rostock) • Prof. Dr. med. Thomas Fuchsluger, FEBO MSc MHBA (Universitäts-Augenklinik Rostock) • Prof. Dr. med. Gerd Auffarth, FEBO (Universität Heidelberg, Heidelberg)(Medical Monitor)