Nova Eye Medical Announces Global Data Registry to Support Role of Canaloplasty for Glaucoma

Adelaide, Australia, 4 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 establishment of the *iTrack™ Global Data Registry* to collect prospective, multicenter, longitudinal data for canaloplasty in the treatment of glaucoma.

A collaboration with the International Glaucoma Surgery Registry (IGSR), *the iTrack™ Global Data Registry* will be led by world-renowned surgeons Iqbal Ike K. Ahmed, MD FRCSC (John A. Moran Eye Center, Utah, USA and Prism Eye Institute, Toronto, Canada), David Lubeck, MD (Arbor Centers for EyeCare, Chicago, USA) and Nathan Kerr, BHB, MBChB, MD, FRANZCO (Eye Surgery Associates, Melbourne, Australia), with the support of an educational grant from Nova Eye Medical.

The i*Track™ Global Data Registry* will capture real-world clinical evidence for canaloplasty across Europe, the Asia Pacific and North America. The Company's portfolio of proprietary canaloplasty devices – the *iTrack™* and *iTrack™ Advance* – will feature in the Registry.

Doctor Kerr is one of the founders of the IGSR and has spearheaded the development of the *iTrack™ Global Data Registry.* He will present an interim data analysis for the *iTrack™ Global Data Registry* during the Asia Pacific Glaucoma Congress (APGC), 4-7 August 2022, in Malaysia.

"The iTrack Global Data Registry is providing high-quality, real-world evidence of the effectiveness and safety of canaloplasty to treat glaucoma and ocular hypertension. Importantly, it provides a robust means by which to collect uniform data to evaluate specified outcomes across the spectrum of glaucoma. It will make a major contribution to our understanding of the clinical effectiveness of canaloplasty and will enable evidence-based decision making," commented Dr. Kerr.

According to Dr. Lubeck, the Registry will ensure the fullest utilization of canaloplasty in daily clinical practice.

“Despite 14 years and tens of thousands of procedures performed globally there is still much to be learned about the nuances and versatility of the canaloplasty procedure. The Registry will address key treatment parameters such as patient specific needs, preferences, type of glaucoma, disease stage and tolerance to prior treatment. The data collected will help guide surgeon decision-making when planning surgery for their glaucoma patients.”

According to Ike Ahmed, MD, FRCSC, the Registry will help surgeons determine when, and how, to use canaloplasty in clinical practice.

“The emergence of new treatment options for glaucoma, including MIGS, and the possibility to intervene earlier in the treatment paradigm is a huge win for both patients and surgeons. With the increased array of available treatment options, however, there is a need to better understand when and how these treatments should be utilized. With the data to be generated by the Registry my hope is that we can build an algorithm to inform on the utilization of canaloplasty.”

Tom Spurling, Managing Director of Nova Eye Medical, addressed the Company’s support of the Registry and why it was important for it to be a surgeon-led initiative.

“We have provided support for the IGSR to accommodate the necessary canaloplasty data but will not be involved in the management of the Registry data. The Registry provides surgeons with a platform through which they can independently document their canaloplasty outcomes. Right from the outset, it was very important that the Registry be surgeon driven. We are grateful for the active commitment, self-direction, and follow-through of all participating surgeons, especially doctors Lubeck, Ahmed and Kerr.”

“We are encouraged by the growing interest in canaloplasty and recognize that more and more surgeons are turning to real-world data to inform their decision-making. The Registry will generate highly coveted real-world data on the effectiveness,

biomechanics, and safety of canaloplasty. Not only do we expect this data to improve surgical outcomes with canaloplasty, but by equipping surgeons with a better understanding of when and how to utilize canaloplasty in their glaucoma surgical toolkit we anticipate that it will drive increased utilization of canaloplasty."

The *iTrack™ Global Data Registry* will follow canaloplasty outcomes for a minimum of 24 months and will enrol more than 300 patients.

IRB Approval information:

- WCG IRB (approval number)- 20200728
- Australian New Zealand Clinical Trials Registry (ACTRN trial number 12620001021965)

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

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ABOUT THE IGSR

The International Glaucoma Surgery Registry (IGSR) was co-founded by Dr. Nathan Kerr, Clinical Lead for glaucoma surgical trials at The Centre for Eye Research Australia (CERA) and Dr. Keith Barton a Consultant Ophthalmologist and Glaucoma Specialist at Moorfields Eye Hospital, London. Launched at the European Glaucoma Society congress in 2018, the IGSR is endorsed by the European Glaucoma Society. Currently, 280 surgeons in over 50 countries have joined the registry, which has been validated by the European Glaucoma Society (EGS) and the Australia New Zealand Glaucoma Society (ANZGS).

For more information on the IGSR, please visit:
https://www.australianclinicaltrials.gov.au/anzctr/trial/ACTRN12620001021965

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 2021, the *iTrack*™ *Advance* leverages the proprietary features of the original *iTrack*™ device but incorporates a new handheld injector design, which improves the overall surgical efficiency of the canaloplasty procedure.

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.

For additional information about the iTrack™ portfolio, including safety information, please visit: www.glaucoma-iTrack.com

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

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