Nova Eye Medical Announces U.S. Market Clearance of the *iTrack™ Advance* Canaloplasty Device

Fremont, USA, April 12, 2023 – 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 that it has been granted U.S. Food and Drug Administration (FDA) 510(k) clearance for its new canaloplasty device, *iTrack™ Advance*.

The *iTrack™ Advance* has been cleared for microcatheterization and viscodilation to reduce intraocular pressure (IOP) in adult patients with primary open-angle glaucoma.

First introduced into the U.S. market in 2008, canaloplasty is a stent-free, minimally invasive glaucoma surgery (MIGS) that works with patient physiology to reduce intraocular pressure in glaucoma patients. Specifically, canaloplasty uses an approach akin to angioplasty to treat blockages in all parts of the eye's drainage channel, referred to as the conventional outflow pathway – trabecular meshwork, Schlemm's canal and collector channels – to improve the physiologic outflow of aqueous humor. This is in contrast to other MIGS procedures, which mechanically alter the outflow of aqueous humor via a stent or tissue removal.

Canaloplasty was first brought to the ophthalmological fore in 2008, following the release of the Company's original iTrack™ canaloplasty microcatheter, which has been used in more than 120,000 canaloplasty procedures globally.

The *iTrack™ Advance* leverages the same proprietary features of the Company's original iTrack™, including a 200-micron illuminated canaloplasty microcatheter, but has been designed for improved surgical efficiency. A key feature of the *iTrack™ Advance* is an ergonomic handpiece.

The Company is grateful for the continued collaboration with a multi-disciplinary group of surgeons, academics, and industry partners, which has underpinned the development of the *iTrack™ Advance*. In particular, the Company was fortunate to benefit from the expertise of prominent canaloplasty surgeon Dr. Mahmoud A. Khaimi, Clinical Professor,

James P. Luton, MD Endowed Chair in Ophthalmology at Dean McGee Eye Institute, University of Oklahoma.

Dr. Khaimi was today the first surgeon in the USA to perform canaloplasty with the new *iTrack™ Advance*. The surgeries were performed at the world-renowned Dean McGee Eye Institute.

“I’ve been given the great opportunity to pair hand in hand with Nova Eye Medical to develop the *iTrack™ Advance*. We’ve taken the original iTrack™ canaloplasty microcatheter and teamed it with an ergonomic handpiece that facilitates improved access into the canal.”

“Thanks to the handpiece, we can advance the microcatheter and then retract it along the full circumference of Schlemm’s canal with much greater efficiency than ever before,” added Dr. Khaimi.

“Another important point is that surgeons will continue to benefit from Nova Eye’s proprietary illuminated microcatheter technology. First debuted with the original iTrack™ and now with the *iTrack™ Advance*, it is the world’s only illuminated canaloplasty microcatheter. Being able to track where the microcatheter is at all times makes a significant impact during surgery. I liken it to driving at night without headlights. You’d never choose to drive without the assurance and safety of headlights.” In the USA, the *iTrack™ Advance* has been cleared for canaloplasty both with and without concurrent cataract surgery. Given the enhanced ease-of-use and ergonomic design, along with the more streamlined nature of the procedure, it is expected that the *iTrack™ Advance* will continue to drive increased surgeon uptake of the canaloplasty procedure.

According to Tom Spurling, Managing Director of Nova Eye Medical, the Company will expand its sales and clinical teams in the U.S. effective immediately, to support the U.S. market introduction of *iTrack™ Advance.*

“The U.S. clearance of *iTrack™ Advance* is a significant milestone for our business and comes at a time when, due to its stent-free, tissue-sparing approach, the canaloplasty procedure is rapidly being adopted into the glaucoma treatment algorithm by a growing number of U.S. glaucoma surgeons and anterior segment surgeons.”

“Our current priority is to get the device into the hands of these adopting surgeons as quickly as possible,” added Mr. Spurling.

The *iTrack™ Advance* will be officially launched in the USA at the American Society of Cataract and Refractive Surgery (ASCRS) in San Diego, May 5-8, 2023.

Outside of the USA, the *iTrack*™ *Advance* has been cleared for use since June 2022 throughout Canada, Australia and Europe, including Germany, where a multi-center, randomized study ("CATALYST", CTN: NCT05564091) is currently underway to evaluate the effectiveness of canaloplasty with the *iTrack*™ *Advance* performed in combination with cataract surgery, as compared to cataract surgery alone. The CATALYST Study is expected to reinforce the clinical utility of canaloplasty in the treatment of mild to moderate glaucoma patients.

For more information about *iTrack*™ *Advance*, including important safety information, visit https://itrack-advance.com/us

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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 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.

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.

iTrack™ and iTrack™ Advance have a US Food and Drug Administration (FDA) 510(k) and CE Mark (Conformité Européenne) for the treatment of open-angle glaucoma.

The iTrack™ Advance canaloplasty device 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 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.

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

Images are available at this link: https://bit.ly/3GAnwyR

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