FOR IMMEDIATE RELEASE

ViaLase Completes Enrollment for the Pivotal VIA-002 Trial of the ViaLase® Laser to Treat Primary Open Angle Glaucoma

The ViaLase Laser combines the precision of femtosecond laser technology and the accuracy of micron-level image guidance to deliver the world’s first femtosecond laser image-guided high-precision trabeculotomy (FLigHT)

ALISA VIEJO, CA — October 30, 2023 — ViaLase, Inc., a clinical-stage medical technology company focused on addressing unmet needs in the conventional glaucoma treatment paradigm, today announced it has completed enrollment of VIA-002, the company’s pivotal trial of the ViaLase® Laser to treat adult patients with primary open angle glaucoma (POAG). The ViaLase Laser combines the precision of femtosecond laser technology and the accuracy of micron-level image guidance to deliver a noninvasive glaucoma treatment called femtosecond laser image-guided high-precision trabeculotomy, or FLigHT.

“We are delighted to have our pivotal trial fully enrolled with a total of 152 patients,” said Tibor Juhasz, PhD, Founder and Chief Executive Officer, ViaLase, Inc. “There is a significant unmet need for a noninvasive, nonpharmacological treatment for glaucoma patients who are not ready for cataract surgery or who have already had cataract surgery and are struggling on medical therapy. We are optimistic that our pivotal trial will demonstrate the safety and efficacy of the first-ever FLigHT treatment performed by the ViaLase Laser. Ultimately, it is our greatest wish to be able to provide an effective noninvasive treatment to the millions of people living with glaucoma, one of the leading causes of irreversible blindness worldwide.”

“VIA-002 is a non-inferiority efficacy study comparing the ViaLase Laser to selective laser trabeculoplasty (SLT),” said Richard Lewis, MD, Chief Medical Officer, ViaLase, Inc. “We are hopeful the results of this trial will be consistent with our first-in-human study, which published data of patients followed out to 24 months. ViaLase believes our technology will give doctors the opportunity to intervene earlier in the treatment paradigm with a potentially safe and effective noninvasive procedure.”

VIA-002 is a prospective, randomized, controlled, multi-center trial of the use of the ViaLase Laser versus SLT in adult patients with POAG. In the study, 152 subjects were randomized to either the ViaLase Laser or SLT. The primary effectiveness endpoint is a reduction in mean unmedicated intraocular pressure (IOP) from baseline to 6 months and 12 months. Secondary effectiveness endpoints are the percentage of eyes with a \( \geq 20\% \) reduction in unmedicated IOP at 6 months and 12 months with no secondary surgical intervention to treat glaucoma, and a reduction in mean number of hypotensive medications from screening to 6 months and 12 months.
About the ViaLase Laser
The ViaLase Laser combines a femtosecond laser and micron-level, high-definition image guidance to deliver a noninvasive glaucoma treatment called femtosecond laser image-guided, high-precision trabeculotomy, or FLigHT. The ability to noninvasively create a conduit between Schlemm’s canal and the anterior chamber is an advantage unique to the FLigHT procedure. This first-of-its-kind technology addresses an unmet need for a noninvasive procedure for patients who would benefit from a non-pharmacological, non-surgical procedure but whose therapeutic goals do not justify the risks of a surgically invasive procedure such as minimally invasive glaucoma surgery (MIGS) or traditional filtration surgery.

About Glaucoma
Glaucoma affects 76 million people worldwide, a number that is expected to increase to 112 million by 2040, and is the second leading cause of irreversible blindness in the world.1,2 Most forms of glaucoma are chronic and, when left undetected or untreated, lead to irreversible vision loss. Early detection and treatment are essential to protecting against vision loss, which results when the optic nerve deteriorates, leading to progressive loss of the field of vision. Lowering IOP and thus reducing visual field progression is the only proven glaucoma treatment today. The current treatment paradigm typically begins with topical eye drops, then may advance to laser therapy or minimally invasive glaucoma surgery (MIGS), before resorting to invasive, traditional filtration surgery.

About ViaLase, Inc.
ViaLase, Inc. is a globally-minded, venture capital-backed, clinical-stage medical technology company located in Aliso Viejo, CA. ViaLase is focused on disrupting the conventional glaucoma treatment paradigm with the introduction of a truly noninvasive image-guided femtosecond laser treatment that enhances glaucoma patient care. With a leadership team that has vast experience developing, designing, manufacturing, and commercializing the first femtosecond lasers for ophthalmic surgery for refractive and cataract patients, ViaLase is now bringing that expertise and innovation to glaucoma patients. ViaLase believes in collaborating closely with health care providers, payers, societies, and patients to inform our product development and commercial activities with the goal of bringing this revolutionary treatment to glaucoma patients across the globe. For more information, visit www.ViaLase.com.

References

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