

April 20, 2022



Samsara Vision to Initiate a U.S. PMA Supplemental Study of the SING IMT™, a New-Generation Technology for Age-Related Macular Degeneration

FAR HILLS, N.J.--(April 20, 2022)--[Samsara Vision](#), a company focused on bringing vision and freedom back to patients with late-stage, age-related macular degeneration (AMD) through advanced visual prosthetic devices, today announced FDA approval to initiate a U.S.-based, PMA supplemental study to evaluate improvements in visual acuity and the safety of its SING IMT™ (Smaller-Incision New-Generation Implantable Miniature Telescope) in people living with late-stage AMD.

The CONCERTO trial will recruit older adults living with stable (non-active neovascularization), bilateral central scotomas (blind spots) due to late-stage AMD and fovea-involving geographic atrophy or disciform scar to receive a SING IMT™ in one eye. Study participants, aged 65 and older, cannot have had previous cataract surgery in the study eye and must agree to post-operative rehabilitation and training. Both the operative and the non-study eye will be assessed pre- and post-operatively over a 12-month period (across five visits). The CONCERTO trial will include up to twenty clinical sites across the United States.

“What’s exciting about this new technology is that the SING IMT™ procedure is performed with a pre-loaded delivery system, which is designed to ensure consistent, predictable insertion of the device using a smaller corneal incision -- an important innovation the company developed since first introducing its novel, FDA approved telescopic implant,” said Marc H. Levy, MD, a neuro-ophthalmologist and orbital surgery specialist at the Sarasota Retina Institute and a CONCERTO study investigator and surgeon.

“People living with late-stage AMD face a reduced quality of life and isolation as their impaired vision prevents them from engaging in the activities of daily living and significant unmet treatment needs remain. At Samsara Vision, we’re focused on bringing innovative, high-performance micro-optical devices to market that offer people living with severe vision disorders, like late-stage AMD, sustainable vision improvements,” said Hayley McKee, PhD, Vice President, Worldwide Clinical and Medical Affairs.

SING IMT™ – Innovation for Late-Stage AMD

Nearly invisible inside the eye, the SING IMT™ is a Galilean style telescope implant designed to improve visual acuity and quality of life for patients with late-stage AMD. It is implanted during typical, out-patient cataract surgery with a corneal incision range between

6.5 mm to 7.5 mm. Images seen in “straight-ahead” vision are magnified 2.7x and projected onto healthy, undamaged areas of the macula in the back of the eye, reducing the impact of the AMD “blind spot” on central vision. Already, the SING IMT™ is approved for late-stage AMD patients who are 55 years of age or older in CE Referenced Countries, but it is not currently FDA approved in the United States.

“The CONCERTO trial initiation advances our goal to bring our novel and life-changing technology to our United States-based ophthalmology partners and their patients,” said Thomas Ruggia, chief executive officer at Samsara Vision. “Clinical studies are the foundation of advancing medical breakthroughs. We look forward to sharing results from CONCERTO and working closely with the U.S. Food and Drug Administration to determine a timely pathway to bring the SING IMT™ to market in the United States.”

The Implantable Miniature Telescope for AMD

Samsara Vision’s first-generation device, the Implantable Miniature Telescope (IMT) by Isaac Lipshitz, was first approved in 2010 and has been implanted in more than 600 patients. The SING IMT™ has identical ultra-precision micro-optics employing first-of-kind bi-convex and bi-concave convergent and divergent micro-lenses, coupled with air lenses that combined with the patient’s cornea create a magnified image onto healthy retinal tissue surrounding the degenerated macula. In previous clinical studies, 90% of IMT-implanted eyes achieved at least a 2-line gain or better in either distance or near best-corrected visual acuity (BCVA) at 12 months, sustained to 24 months. Quality of life (NEI-VFQ-25) scores were also improved by clinically significant levels.

Age-related macular degeneration (AMD) is a [leading cause](#) of permanent vision loss for people age 50 and older, and the [number one cause](#) of blindness in people age 65 years and older. As many as [11 million](#) Americans are affected by some form of macular degeneration and this number will increase to 22 million [by 2050](#). Nearly [2 million](#) Americans have advanced forms of AMD with associated vision loss. While treatments exist to try to slow the progression of AMD and there are assistive devices that can help people with reduced vision see better with magnification or more light, many patients will progress in their disease. There is no cure for Late-Stage AMD.

The IMT is not a cure for late-stage AMD. It will not return vision to the level a patient had before AMD, nor will it completely make up for vision loss. The most common risks of the IMT and SING IMT™ surgery include inflammatory deposits or precipitates on the device and increased intraocular pressure. Significant adverse events include corneal edema, vision-impairing corneal edema, corneal transplant, and decrease in visual acuity. There is a risk that having the telescope implantation surgery could worsen your vision rather than improve it. Individual results may vary.

About Samsara Vision

Samsara Vision is a privately held specialty medical device company headquartered in the United States and engaged in the research, development, manufacture, and marketing of proprietary implantable ophthalmic devices and technologies that are intended to significantly improve vision and quality of life for individuals with untreatable retinal disorders. We believe that rejuvenating eyesight revives the spirit, allowing people to reconnect to the things in life that they love to see and do. Our approach includes working collaboratively with

health care providers, researchers, payers, and advocates to ensure that people living with deteriorating vision have access to our novel technologies and support paths thereby better ensuring a future where they can see anew. Learn more at <https://www.samsaravision.com>

Safe Harbor Statement

This press release contains express or implied forward-looking statements pursuant to U.S. Federal securities laws. Forward-looking statements include those about the belief that the company's name change better reflects Samsara's patient centricity and focus and the belief that rejuvenating eyesight revives the spirit, allowing people to reconnect to the things in life that they love to see and do. These forward-looking statements and their implications are based on the current expectations of the management of Samsara only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: claims by other companies and persons regarding ownership over intellectual property; changes in technology and market requirements; Samsara may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Samsara's products may not be approved by regulatory agencies, Samsara's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Samsara may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Samsara's process; Samsara's products may wind up being more expensive than it anticipates; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; Samsara's patents may not be sufficient; Samsara's products may harm recipients; changes in legislation may adversely impact Samsara; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause the actual results or performance of Samsara to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Samsara undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Media Contact:

Jessica Daitch
Jessica L. Daitch Communication LLC
For Samsara Vision
917-816-6712
jessicadaitch@hotmail.com