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Samsara Vision Announces Positive Six-Month Visual and Safety Outcomes from the SING IMT® (Smaller-Incision New-Generation Implantable Miniature Telescope)

Published Study Reports Near Distance Reading Ability Increased from 28.6% to 97.1%

FAR HILLS, N.J.--(BUSINESS WIRE)-- 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 reported intermediate-term visual and safety outcomes of the SING IMT® (Smaller-Incision New-Generation Implantable Miniature Telescope) in patients six months post-surgery. Overall, researchers found that SING IMT implantation improved distance and near vision, with a low impact on the corneal endothelium cell density and manageable safety outcomes. These positive results also just published in the journal *Heliyon*.

Researchers reported that at six months post-surgery, at least 1-, 2-, and 3-line gains in best-corrected distance (BCDVA) were achieved in 97.1 percent, 68.6 percent and 51.4 percent of operated eyes, respectively (n=35), with the mean ± standard deviation (SD) change in BCDVA from baseline - 0.29 ± 0.142. The percentage of patients able to read at near distance increased from 28.6 percent at baseline to 97.1 percent at six months. In addition to distance vision, the study also found that corrected near visual acuity was also significantly improved by ⁓3 lines at 6 months post-surgery.

“Already, nineteen CE referenced countries have implanted the SING IMT in more than 400 patients, with greater than 63 percent of surgeons performing multiple procedures, signaling increasing physician confidence and enthusiasm for the procedure,” said Thomas Ruggia, president and CEO of Samsara Vision. “We’re gratified that this study confirms the effectiveness and safety of the SING IMT and believe our novel device will become the standard of care for patients blinded in their central vision by AMD.”

Learning to Use SING IMT

Approved for use in CE Mark referenced countries, the retrospective SING IMT study included 35 patients (55 years or older) with late-stage AMD, treated at either the University Federico II in Naples, Italy or the Policlinico Gemelli hospital in Rome, Italy. To optimize the visual outcomes, patients participated in a required rehabilitation program starting six weeks

after surgery, attending eight 90-minute sessions every two-to-three weeks for six months. The program included exercises to strengthen skills such as visual abilities, reading, writing, visual motor integration, and mobility.

Notably, there was no clinically meaningful change from baseline in intraocular pressure or anterior chamber depth (ACD) and the mean (SD) change from baseline in corneal endothelial cell density (ECD) at six months in operated eyes was -280.7 (315.9) cells/mm2 (-11.4 %). Importantly, no new complications occurred between the 3- and 6-month follow-ups. Most expected adverse events, such as corneal edema (22.9%), resolved by 6 months with the use of topical medications, while some device-related events (e.g., iris damage, pigment deposits) persisted, indicating an acceptable safety profile for SING IMT implantation.

"This six-month review highlights the potential of SING IMT to restore meaningful vision to individuals blinded by AMD, while preserving long-term corneal health with its innovative design," said Prof. Toro, co-author of the study from University Hospital Federico II, Naples, Italy.

Study co-author Prof. Savastano, Regional Hospital “F. Miulli”, Acquaviva delle Fonti (BA), Italy, added, "We will continue monitoring these patients to ensure their improved vision translates into a better quality of life and enhanced daily functioning.”

Among several studies published in 2024, an especially pertinent one was a small retrospective study (n=11) published in Ophthalmology and Therapy that evaluated functional vision approvements following SING IMT implantation. The study reported significant improvement in real-world tasks such as reading, writing, visual motor integration and mobility, a key predictor of patient-reported visual ability and vision-related quality of life.

Addressing Unmet Treatment Needs in AMD

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. Similarly, approximately 67 million people in the European Union are affected by AMD and this number is expected to grow by 15 percent until 2050. 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, many patients will progress in their disease. The SING IMT is an intraocular telescope approved for use in patients without previous cataract surgery and 55 years and older in CE Referenced countries and is under investigation in the United States.

There is no cure for late-stage AMD and the SING IMT® does not return vision to the level a patient had before AMD, nor will it completely make up for vision loss. Driving is contraindicated with the device. The most common risks of the SING IMT® surgery include inflammatory deposits or precipitates on the device and increased intraocular pressure. Adverse events in the recent study include corneal edema, and one patient had a decrease in visual acuity. There is a risk that having the telescope implantation surgery could worsen 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 potential benefits to be derived from the SING IMT™ and the intent to work closely with the FDA to determine a timely pathway to bring the SING IMT™ to market in the United States 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; the risk factors and uncertainties described in the Registration Statement on Form S-1, as amended (File No. 333-260742) filed with the U.S. Securities and Exchange Commission; 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.

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Jessica Daitch
JLD Communication LLC

For Samsara Vision
917-816-6712
jessica@jldcommunications.com

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