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Samsara Vision Announces CE Mark Approval of the Tsert-SI™ Delivery System for the CentraSight Treatment Program

The Telescope Implant for End-Stage Macular Degeneration is Approved and Available Around the World for Eligible Patients Without Previous Cataract Surgery

Saratoga, CA – (May XX, 2020) —Samsara Vision a developer of advanced visual prosthetic devices for the treatment of age-related macular degeneration (AMD), today announced that receipt of a Conformité Européene (CE) Mark for the Tsert-SI™ delivery system for the CentraSight treatment program. The CentraSight treatment program includes the Implantable Miniature Telescope (by Dr. Isaac Lipshitz), which is available around the world, including the United States, Europe, Australia, New Zealand, and Israel. The Tsert-SI delivery system includes a pre-loaded telescope implant injector, which only requires a 6.5mm incision, reducing the incision size by nearly half.

“The Tsert-SI delivery system will allow surgeons to more quickly and more easily insert the telescope implant, which is demonstrated to restore vision and improve quality of life in people living with severe, blinding forms of macular degeneration” said Sumit Garg, MD, Associate Professor of Ophthalmology, Medical Director, and Vice Chair of Clinical Ophthalmology at the Gavin Herbert Eye Institute (University of California, Irvine). “With a smaller incision size, the surgery will be more straightforward, and patients will have a faster visual recovery.”

The Tsert-SI delivery system includes a telescope implant with foldable haptics, which allows it to fit in the injector and be delivered through a smaller incision. During development, providers found that out-patient surgery procedural time using the injector system, which includes removal of a patient’s cataract and implantation of the implantable miniature telescope in one eye only, expected to drop from approximately 60 minutes to approximately 25 minutes (in routine procedures).

”We are excited that our years long effort to develop the Tsert-SI delivery system will allow ophthalmologists in the European Economic Area to offer the telescope implant and CentraSight treatment program to their patients with the goal of an enhanced patient experience,” stated Wolfgang Tolle, CEO of Samsara Vision “We look forward to coordinating a meeting with the U.S. Food and Drug Administration to determine the timeline and pathway to bring this technology to United States health care providers.”

In the United States, the telescope implant is part of the CentraSight® treatment program, which is for people 65 years and older diagnosed with end-stage, age-related macular degeneration who meet specific eye health and vision requirements, and for whom common

treatments such as glasses, vitamins, drugs or cataract surgery will not lead to vision improvement. The telescope implant is contraindicated in patients with previous intraocular or corneal surgery of any kind in the operative eye, including cataract surgery.

About CentraSight and the Telescope Implant
The Implantable Miniature Telescope (by Dr. Isaac Lipshitz) is indicated for monocular implantation to improve vision in patients who meet age requirements and with stable severe to profound vision impairment (best-corrected distance visual acuity 20/160 to 20/800) caused by bilateral central scotomas (blind areas) associated with End-Stage AMD.

This level of visual impairment constitutes statutory (legal) blindness. Smaller than a pea, the telescope is implanted in one eye in an outpatient surgical procedure. In the implanted eye, the device renders enlarged central vision images over a wide area of the retina to improve central vision, while the non-operated eye provides peripheral vision for mobility and orientation. The telescope implant is part of the CentraSight treatment program, which has been designed to help patients follow the necessary steps for proper diagnosis, surgical evaluation, and postoperative care.

The telescope implant is not a cure for End-Stage AMD. As with any medical intervention, potential risks and complications exist with the telescope implant. Possible side effects include decreased vision or vision-impairing corneal swelling. The risks and benefits associated with the telescope implant are discussed in the Patient Information Booklet available at www.CentraSight.com and will be evaluated with each patient who might be a candidate for this study.

Patients and physicians can find more information about the telescope implant and related treatment program by visiting www.CentraSight.com or calling 1-877-997-4448.

Media Contact:
Jessica Daitch
Samsara Vision
917-816-6712
jessicadaitch@hotmail.com