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Samsara Vision Announces Regulatory Approval of the CentraSight Treatment Program in Australia

The Telescope Implant for End-Stage Macular Degeneration is Approved and Available Around the World in Patients Who Meet Age Requirements and Who Have Not Had Cataract Surgery

SARATOGA, Calif.—([BUSINESS WIRE](#))—Samsara Vision, a developer of advanced visual prosthetic devices for the treatment of age-related macular degeneration (AMD), today announced that the Australian Department of Health Therapeutic Goods Administration has issued a Therapeutic Goods Certificate to the Implantable Miniature Telescope (by Dr. Isaac Lipshitz), approving it for the improvement of visual acuity in patients who are 55 years and older with bilateral moderate to profound central vision impairment due to age-related macular degeneration. According to Macular Disease Foundation Australia, macular degeneration is the leading cause of legal blindness and severe vision loss in Australia, responsible for 50 percent of all cases of blindness.¹

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.

“We are excited that ophthalmologists can begin to offer the [Implantable Miniature Telescope](#) to older adults in Australia whose central vision is severely impaired by end-stage macular degeneration,” stated Blake Michaels, President and CEO of Samsara Vision “The telescope implant is proven to improve vision and quality of life, and it is very gratifying to be able to offer our device and the comprehensive treatment program now to patients in this market.”

CentraSight Available Around the World

The telescope implant is the only FDA-approved surgical device for advanced macular degeneration and is Medicare eligible. Beyond the United States, it also holds the CE Mark, Health Canada Licence and is approved for use in, Israel, New Zealand and now, Australia. It is manufactured in an FDA registered facility.

Last month, the very first telescope implant procedure was performed in Canada by corneal surgeon, Richard Bazin, M.D., FRCSC at the Saint-Sacrement Hospital in Quebec.

Samsara Vision is also conducting a clinical investigation in the United States to evaluate the safety and effectiveness of exchanging a previously implanted intraocular lens (IOL) with the telescope implant. According to current U.S. labeling, 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.

1 About Macular Degeneration. Macular Degeneration Foundation Australia. Last accessed on February 20, 2019. <https://www.mdfoundation.com.au/content/what-is-macular-degeneration>

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