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Five-Year Data Demonstrates Long Term Effectiveness and Safety of Samsara Vision's Telescope Implant for Macular Degeneration in Patients 65 Years and Older

David S. Boyer, MD to Present Data at Upcoming American Society of Retina Specialists (ASRS) 33rd Annual Meeting

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Samsara Vision Ophthalmic Technologies, Inc. a developer of advanced visual prosthetic devices for the treatment of age-related macular degeneration (AMD), today announced the publication of “Long-Term (60-month) Results for the Implantable Miniature Telescope: Efficacy and Safety Outcomes Stratified by Age in Patients with End-Stage Age-Related Macular Degeneration” in [Clinical Ophthalmology](#). The 5-year data show substantial retention of gains in visual acuity over time after implantation with the [Implantable Miniature Telescope](#) (“IMT” by Dr. Isaac Lipshitz). The study reported that both younger (aged 65 to <75) and older patients (aged 75+) had clinically significant visual acuity gains at 2 years as well as 5 years after telescope implant. Younger patients retained more of the vision gains at five years and experienced somewhat fewer adverse events.

The data from this long-term study supported a labeling indications expansion request that resulted in an October 2014 U.S. Food and Drug Administration (FDA) approval to include patients between the ages of 65 and 74, in addition to those 75 and older. The telescope implant is the only FDA-approved, Medicare-eligible surgical device to treat the most advanced form of AMD.

“These data demonstrate that the telescope implant is a clinically meaningful treatment option for patients with cataracts who have bilateral age-related macular degeneration associated with central vision loss,” stated David S. Boyer, M.D., vitreoretinal specialist at Retina-Vitreous Associates Medical Group in Beverly Hills, CA and lead author. “The fact that these 65 to 74 year-old patients, on average, retained nearly three lines of improvement five years after telescope implantation is tremendous.”

Notably, at the upcoming American Society of Retina Specialists (ASRS) 33rd Annual Meeting, Dr. Boyer will offer the first presentation of the conference – “Long-Term (60-month) Results of the Implantable Miniature Telescope” on July 11 at 8:05 a.m. CET (Central European Time) in Vienna.

About the Study

Patients participating in the company's 24-month pivotal safety and efficacy study, IMT-002, were invited to participate in the IMT-002-LTM extension study. Of the 217 end-stage macular degeneration patients enrolled in IMT-002, 129 participated in the long-term evaluation of the telescope implant. Patients were followed through 60 months after telescope implantation. Efficacy and safety data were analyzed for the entire patient population and were also stratified by age for two patient groups, those age 65 to 74 and those age 75 and older.

Overall, study authors reported there was a clinically significant gain in visual acuity (mean 3.2 lines of gain on visual charts) at 2 years after telescope implantation and most of the gain in visual acuity was maintained (mean 2.4 line improvement) at five years after telescope implantation. Retention of the clinically significant 2-line visual acuity gain was somewhat higher in younger patients as compared to older study participants (68% versus 59%, respectively) at the conclusion of the five year study.

With respect to adverse events, only 7% of patients, at their last study exam, had visual acuity loss of more than 2 lines in telescope implanted eyes. Visual acuity loss was somewhat higher in older patients than younger patients (8% versus 6%). In younger and older groups two patients in each group underwent corneal transplant (2% and 3%, respectively). Overall, adverse events were somewhat higher in the older group of patients.

"We develop long-term relationships with our patients living with AMD, trying to slow their progression, but, unfortunately, many still progress to this advanced stage," said Carl D. Regillo, M.D., Director of Retina Service, Wills Eye Hospital. "With this data and the corresponding age-related expanded indication by the FDA, retina specialists should consider recommending their end-stage AMD patients for surgery so that they may potentially benefit from better vision and improved quality of life sooner." Drs. Boyer and Regillo were also joined by co-authors K. Bailey Freund, MD., Vitreous-Retina-Macula Consultants of New York, Marc H. Levy, M.D., Sarasota Retina Institute, and Sumit Garg, M.D., The Gavin Herbert Eye Institute, University of California, Irvine.

About CentraSight and the Telescope Implant

The telescope implant is the integral component of Samsara Vision's comprehensive treatment program called [CentraSight®](#), which helps patients follow the steps necessary for proper diagnosis, surgical evaluation, implantation and postoperative care.

The Implantable Miniature Telescope (by Dr. Isaac Lipshitz) is indicated for monocular implantation to improve vision in patients greater than or equal to 65 years of age 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 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 at www.CentraSight.com.

Patients and physicians can learn more about the telescope implant by visiting www.CentraSight.com or calling 1-877-99-SIGHT.

About End Stage AMD

AMD is the leading cause of vision loss in Americans aged 60 and older, affecting an estimated 15 million people.ⁱ Of those, 2 million Americans are living with end-stage AMDⁱ and that number will increase as the Baby Boomer cohort ages.ⁱ End-stage AMD is uncorrectable by any other treatment including glasses, vitamins, drugs or cataract surgery and is associated with increased stress and depression as vision diminishes.ⁱⁱ

About Samsara Vision Ophthalmic Technologies

Samsara Vision Ophthalmic Technologies, Inc., headquartered in Saratoga, CA, is a privately-held company. The Company is focused on the development, manufacturing, and marketing of implantable ophthalmic devices and technologies that are intended to improve vision and quality of life for individuals with end-stage age-related macular degeneration.

ⁱVision Problems in the United States. Prevent Blindness America. Accessed on September 19, 2014 at <http://www.visionproblemsus.org/amd/amd-map.html>

ⁱⁱ Bennion, AE, Shaw, RL, Gibson, JM “What do we know about the experience of age related macular degeneration? A systematic review and meta-synthesis of qualitative research?” Social Science & Medicine. 75 (2012) 976-985.

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