January 10, 2017

FDA Grants Samsara Vision Approval to Initiate Clinical Study of the Telescope Implant in Post-Cataract Patients

Telescope Implant for End-Stage Macular Degeneration is Already FDA Approved and Available to Patients 65 Years and Older Who Have Not Had Cataract Surgery

SARATOGA, CA–(Marketwired – January 10, 2017)

Samsara Vision a developer of advanced visual prosthetic devices for the treatment of age-related macular degeneration (AMD), today announced the U.S. Food and Drug Administration (FDA) approved the company's investigational device exemption for a new U.S. clinical study. The study will evaluate the safety and effectiveness of the telescope implant in patients who were previously implanted with an intraocular lens (IOL). In the study the IOL will be exchanged for the Implantable Miniature Telescope (by Dr. Isaac Lipshitz).

Under current indications the telescope implant is proven to improve visual acuity and quality of life for patients with End-Stage macular degeneration whose sight is permanently obstructed by a blind spot in their central vision (in both eyes), making it difficult or impossible to see faces, read, and perform everyday activities such as watching TV, preparing meals, and self-care.1 It is the only FDA approved surgical device for End-Stage macular degeneration and is Medicare eligible.

According to current labeling, the telescope implant is contraindicated in patients with previous intraocular or corneal surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes. Specifically, the new study will evaluate the safety and effectiveness of the telescope implant in patients who were previously implanted with an intraocular lens.

Selected CentraSight providers across the country are now seeking End-Stage macular degeneration patients with previous cataract surgery to determine if they might be candidates as study subjects for the telescope implant.

"Cataract surgery is often performed on patients living with macular degeneration in the hopes that an IOL will improve contrast and light. However, studies show that patients who progress to End-Stage macular degeneration do not experience an appreciable improvement in their visual acuity, post cataract surgery," said Stephen Lane, MD. "The long term efficacy of the telescope implant in improving vision and quality of life in AMD patients has been demonstrated during studies that followed subjects up to 8 years post-surgery. This study will inform us about the safety, effectiveness, and the appropriate surgical

technique for implanting the telescope in patients who have had cataract surgery before."

Unmet Macular Degeneration Treatment Needs
Macular degeneration is the leading cause of permanent vision loss in Americans aged 60 and older, affecting an estimated 15 million people.1Of those, 2 million Americans are living with End-Stage AMD2 and that number will increase as the Baby Boomer cohort ages.1 End-Stage macular degeneration cannot be corrected by any other treatment including glasses, vitamins, drugs or cataract surgery and is associated with increased stress and depression as vision diminishes.3

"We developed the telescope implant to help older adults with severely impaired central vision live more independently and improve their vision. Hundreds of patients have experienced the CentraSight treatment program and learned to use their new, improved vision, effectively," said Blake Michaels, President & CEO of Samsara Vision. "We hope the results of this study will allow us to offer the telescope implant to an even broader population of patients who are currently excluded simply because they had a routine eye surgery in the past. We're looking forward to advancing this study and analyzing the results."

About CentraSight and the Telescope Implant
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. The device holds FDA (PMA) approval, CE Mark, Health Canada Listing and is manufactured in an FDA registered facility.

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 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.

CONTACT:
Jessica Daitch
Jessica L. Daitch Communications LLC
704-321-0813 (work)
917-816-6712 (cell)
jessicadaitch@hotmail.com

1 What is AMD? Macular Degeneration Partnership. Accessed on Nov 3, 2016

at http://www.amd.org/what-is-macular-degeneration/

2 Vision Problems in the United States. Prevent Blindness America. Accessed on November 3, 2016 at http://www.visionproblemsus.org/amd/amd-map.html

3 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.