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First Patient in the Nation Receives a Telescope Implant for Age-Related Macular Degeneration after Previous Cataract Surgery

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 – (BUSINESS WIRE) — VisionCare, Inc. ("VisionCare"), a developer of advanced visual prosthetic devices for the treatment of age-related macular degeneration (AMD), today announced that the first patient in its clinical investigation to evaluate the safety and effectiveness of exchanging a previously implanted intraocular lens (IOL) with the Implantable Miniature Telescope (by Dr. Isaac Lipshitz) was successfully completed. The U.S. Food and Drug Administration (FDA) approved the company's investigational device exemption for this new U.S. clinical study in January 2017. 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 cataract surgery.

The surgery took place on August 29, 2017 at the Ridge Lake Ambulatory Surgery Center in Memphis, TN. Dr. Subba Gollamudi, M.D. of Eye Specialty Group performed the surgery in one of his female patients.

"The procedure to exchange an IOL for the telescope implant went well," said Dr. Gollamudi. "We are excited to see this patient's progress as she learns to use this remarkable device. In my practice, telescope implant patients have resumed hobbies, lived more independently and, most importantly, have been able to see the faces of their family and friends again."

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. Dr. Gollamudi's patient is one of 50 that VisionCare will evaluate to determine, in collaboration with the FDA, if the study will expand to a large-scale investigation.

Macular Degeneration is Challenging to Treat

Macular degeneration is the leading cause of permanent vision loss in Americans aged 60 and older, affecting an estimated 15 million people. Of those, 2 million Americans are living with End-Stage AMD and that number will increase as the Baby Boomer cohort ages. 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.

“Hundreds of patients with severely impaired central vision have experienced the CentraSight treatment program and learned to use their new, improved vision effectively,” said Blake Michaels, President & CEO of VisionCare, Inc. “As the year advances and we identify additional patients for surgery, we hope that the study results will help us answer questions about the population of patients for whom the CentraSight program is appropriate. We are aware that many people living with end-stage AMD are quickly 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 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. It is the only FDA-approved surgical device for End-Stage macular degeneration and is Medicare eligible. It also holds a 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 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 1-855-550-1041.

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