



FOR IMMEDIATE RELEASE

**REFOCUS GROUP COMPLETES PHASE 3 CLINICAL TRIAL ON THE VISABILITY™
MICRO-INSERT SYSTEM FOR PRESBYOPIA; RAISES ADDITIONAL FUNDING**

360 Patient Surgeries Completed; 12-Month Follow-Up in Process

DALLAS (May 5, 2016) – [Refocus Group](#), a pioneer in vision-correcting technology, announced today that it has completed the enrollment of its Phase 3 clinical trial on the [VisAbility™ Micro-Insert System](#) for presbyopia, and secured an additional \$15 million in new financing from MedCare Investment Funds and WP Global Partners. Mike Judy, CEO of Refocus Group, made the announcement today at the 2016 Ophthalmology Innovation Summit at American Society of Cataract and Refractive Surgeons Annual Symposium and Congress (OIS/ASCRS) in New Orleans.

Nearly 90 million Americans and 1.7 billion people worldwide are affected by presbyopia. Presbyopia causes the inevitable loss of near vision after age 40, making it difficult to read, do hobby work or use a cell phone without the aid of reading glasses.

The VisAbility Micro-Insert System is the first and only presbyopic procedure performed outside the eyes line-of-sight developed to restore near vision without any compromise to distance vision or depth perception, a potential drawback of other presbyopic treatments. Because the procedure is performed in the sclera (white part of the eye), the VisAbility Micro-Insert System doesn't alter the cornea or natural lens, so the eye is preserved for future refractive or cataract procedures.

“When you consider that the VisAbility Procedure is done outside the visual axis without affecting the cornea or crystalline lens, it could be considered one of the most promising, *least-invasive* presbyopic procedures in ophthalmology,” said David Schanzlin, MD, Partner, Gordon Schanzlin New Vision Institute, San Diego. “It could offer all the gain of presbyopic correction without the compromises our patients have encountered with other presbyopic treatments.”

The VisAbility™ Procedure is performed on both eyes and consists of inserting four, micro-thin inserts, smaller than a grain of rice, just below the surface of the sclera. The inserts are designed to restore the eye's natural ability to bring near vision back into focus.

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The inserts are so small they can't be felt, and are unnoticeable to others in normal gaze. The VisAbility Micro-Insert System is performed as an outpatient procedure with topical (eye drop) anesthesia.

"A presbyopia-correcting procedure where there is no compromise of distance vision or sacrifice of light offers something truly different than what is available today," said Dr. Ralph Chu, Founder and Medical Director of Chu Vision Institute and Chu Surgery Center, Bloomington, MN. "I think refractive surgeons should pay close attention to the proposed benefit the VisAbility Micro-Insert System delivers to both the patient and practice, compared to other available and emerging presbyopic correcting procedures."

The VisAbility™ Micro-Insert System

The VisAbility Micro-Insert System is one of the most thoroughly studied presbyopic treatments in ophthalmic history. Promising outcomes kept investigators intrigued, as the technology improved and the technique evolved. The technology was officially branded VisAbility™ in late 2014.

"The VisAbility Micro-Insert System has been refined with considerable advancements to both the design and surgical technique that have made the procedure faster and more precise, with consistent outcomes and happy patients," said Karl Stonecipher, MD, Medical Director of TLC Laser Eye Centers of Greensboro, NC. "We have been able to get the procedure time under 20 minutes, and that currently includes time for measurements and data collection required for the trial."

The current clinical trial, "A Prospective, Multicenter Clinical Trial of The VisAbility Implant System for Improvement of Near Visual Acuity in Presbyopic Patients," enrolled a total of 360 subjects between 45 and 60 years of age at 13 clinical sites in the US. Given the substantial clinical trial history and previous data on the device, the FDA has granted Refocus Group a 12-month follow-up for approval, versus the usual 24 months. With enrollment complete, Refocus expects to submit for FDA premarket approval in 2017.

NEW FUNDING CONTINUES TO VALIDATE INVESTOR CONFIDENCE

Refocus Group recently closed a new round of financing to support trial completion and premarket approval. Investors include MedCare Investment Funds and its affiliates which manage approximately \$1 billion in assets, the substantial majority related to the medical and healthcare services industry; and Chicago-based WP Global Partners, one of the most-experienced teams in the private equity industry, investing well over \$5.6 billion in partnerships and co-investments on behalf of major institutional clients. Don Phillips, WP Global Partners Chairman and CEO, will serve on the Refocus Group Board of Directors.

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“I am happy to welcome Don Phillips to our board, and am confident that his vast experience in guiding successful businesses will be an asset to Refocus Group,” said Mike Judy, Refocus Group CEO. “With the overwhelming support of investors and the trial enrollment complete, we are poised to finish patient follow-up, submit for FDA approval and prepare for commercialization. The VisAbility Procedure is the presbyopic solution that doctors and patients have been waiting for, one designed to offer near-vision correction without compromise.”

ABOUT REFOCUS GROUP INC.

Refocus Group Inc. is a pioneer in vision-correcting technology and is the developer of the VisAbility™ Micro-Insert System, an investigational medical device currently undergoing clinical trials in the United States, that may be able to restore the natural ability to focus on objects up close and eliminate the need for reading glasses. The company is headquartered in Dallas. For more information, please visit www.refocus-group.com.

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