



## The KAMRA™ Inlay Receives FDA Approval

IRVINE, CA – April 17, 2015 – AcuFocus, Inc., the global leader in corneal inlay technology announced today that the United States Food and Drug Administration has approved its groundbreaking product, the KAMRA inlay. The KAMRA inlay is indicated to improve near vision by extending depth of focus in presbyopic patients who have emmetropic refractions (+0.50 D to -0.75 D). This approval represents the first major advancement in the surgical correction of presbyopia in well over a decade.

Presbyopia is the age-related loss of near vision that affects virtually everyone over age 50. Researchers estimate that more than 114 million people in the United States, including the entire Baby Boomer generation, have presbyopia.<sup>1</sup> This estimate is expected to grow to more than 123 million by 2020. Today, most people with presbyopia must rely on reading glasses to see objects up close.

“The KAMRA inlay is the number one implanted corneal inlay globally,” said Jim Mazzo, Chairman and CEO of AcuFocus, Inc. “After a decade of research, development and clinical investigation, we are delighted to bring this innovative technology to surgeons and patients in the U.S.”

The KAMRA inlay approval was based on the results of 508 patients treated at 24 investigational sites worldwide. Patients in the clinical study experienced an average improvement in uncorrected near visual acuity of 3.0 lines between their pre-op exam and the 12-month follow-up visit. This improvement was maintained over the 5-year duration of the study. Mean pre-operative uncorrected distance visual acuity in the inlay-implanted eye was maintained across all follow-up exams, unlike other presbyopia correcting procedures where distance vision is compromised in order to improve near vision.

“Near-vision loss from presbyopia can be a significant challenge in the everyday lives of patients, especially those who are emmetropic, which means they previously enjoyed normal vision without the need for glasses, contacts or other correction,” said Daniel S. Durrie, MD, founder of Durrie Vision, Overland Park, Kansas. “With the approval of the KAMRA inlay, we now have a reliable solution for presbyopes who want to enjoy many daily activities without reading glasses.”

The KAMRA inlay is an ultra-thin opaque ring that is implanted monocularly into the patient’s non-dominant eye. The device utilizes the principle of small aperture optics, or pinhole effect, to extend depth-of-focus for patients suffering from age-related near vision loss. The inlay measures 3.8 mm in total diameter and has a 1.6 mm central

aperture. As a result of this novel design, central focused light is allowed to reach the retina uninterrupted resulting in functional vision from near to far without reading glasses.

“Surgical options for patients frustrated with near vision loss have previously been limited and often required patients to accept compromises like loss of effect over time,” said John Vukich, MD, Associate Clinical Professor at the University of Wisconsin-Madison Medical School, Madison, Wisconsin. “With the KAMRA inlay now available in the United States, we have a safe, effective and long-term solution for presbyopes that is designed especially for their needs.”

The company will host an educational event on the KAMRA inlay at the upcoming American Society of Cataract and Refractive Surgeons (ASCRS) annual meeting in a company sponsored Corporate Morning symposium on Saturday, April 18<sup>th</sup> beginning at 8:30am at the San Diego Convention Center, Room 8. Wet lab and product demonstrations will be available at the AcuFocus exhibit booth #317. More information about these events is available at [www.acufocusevents.com](http://www.acufocusevents.com).

### **About AcuFocus**

AcuFocus Inc. is a privately held ophthalmic medical device company that develops and markets breakthrough technologies for the improvement of near vision. The Company’s proven, proprietary technology platforms use a small aperture – or pinhole – effect to allow only focused light rays to reach the retina and bring objects into focus. The result is unique, reliable and long-term. Using the small aperture concept, two products have been developed: the Company’s flagship product the KAMRA™ corneal inlay and the innovative IC-8™ IOL. The KAMRA inlay helps presbyopic patients restore their near vision while maintaining their distance vision. It is commercially available in 50 countries, including the United States. The IC-8 IOL provides a range of vision across various distances, from near to far, and is specifically designed for patients with cataracts. The IOL is CE Marked and currently available in select markets. It is not yet approved by the FDA for use in the U.S. In addition to these products, AcuFocus also distributes the AcuTarget HD™ diagnostic and surgical planning instrument. This instrument is essential for the optimal treatment and technology selection for a broad range of patients, including LASIK, cataract, dry eye and presbyopes. Founded in 2001, AcuFocus is based in Irvine, CA. For more information, visit [www.AcuFocus.com](http://www.AcuFocus.com).

***The KAMRA corneal inlay*** provides a long-term solution for presbyopia. Presbyopia will impact virtually everyone over the age of 50 and will affect nearly 2.1 billion people worldwide by 2020<sup>1</sup>. The inlay is a microscopically small and thin device that sits comfortably in the cornea. It measures just 3.8 mm in diameter with a 1.6 mm center opening that enables light to move directly from the front of the eye to the back of the eye, providing a natural range of vision from near to far without blurry zones. The center aperture is surrounded by 8,400 perforations that allow oxygen and nutrients to

flow freely and naturally through the eye. Moreover, it continues to be effective over time, even as presbyopia progresses. It is approved in the U.S. and commercially available in 50 countries worldwide. The KAMRA™ inlay is an ideal solution for active presbyopes who want to recapture their everyday vision and enjoy freedom from the constant frustrations of reading glasses.

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<sup>†</sup> Market Scope, *The Comprehensive Report on The Global Market for Presbyopia-Correcting Surgery*, 2014