



For Immediate Release
Contact: Silvana Guerri-Lena
Pascale Communications
508-808-8993

silvana@pascalecommunications.com

AcuFocus Receives IDE Approval from the U.S. FDA to Begin Clinical Study of the IC-8® Lens

IRVINE, Calif. – (November 26, 2018) – AcuFocus, Inc., a privately held ophthalmic medical device company, announced today that it has received approval for an Investigational Device Exemption (IDE) from the U.S. Food and Drug Administration (FDA) to conduct a pivotal study of the company's **IC-8** small aperture intraocular lens (IOL) for patients with cataracts.

An estimated 90% of people worldwide have begun to develop clouding in the eye's natural lens—cataracts—by the time they become 65 years of age. If left untreated, cataracts lead to a loss of vision over time. The only treatment for cataracts is the surgical removal of the natural lens and replacement with an IOL. Most cataract patients are treated with a standard monofocal (single-focus) lens, which gives them excellent far vision, but they remain dependent on glasses for near and intermediate vision.

The AcuFocus **IC-8** IOL is a clear monofocal lens with an embedded mini-ring or pinhole in the center. This novel lens is designed to increase a patient's natural range of vision by extending the focus of light rays that enter the eye.

"Studies performed outside the United States have shown that the **IC-8** lens delivers reliable extended depth of focus with high levels of patient satisfaction," said Al Waterhouse, AcuFocus Chief Executive Officer. "Achieving IDE approval was the next critical milestone for the company as we seek premarket approval in the United States"

The goal of this prospective, multicenter, parallel-group study is to demonstrate the extended depth of focus achieved with the **IC-8** IOL when compared with traditional monofocal IOLs. The study will enroll approximately 475 patients with bilateral cataracts. Participants will be followed for 12 months and evaluated for improvement in their vision at all distances.

ABOUT ACUFOCUS

AcuFocus, Inc., is a privately held ophthalmic medical device company that develops and markets breakthrough technologies for the improvement of vision. The **IC-8** IOL received CE mark in 2014 and is available in select markets across Europe and Asia. Founded in 2001, AcuFocus is based in Irvine, Calif. For additional information about the **IC-8** intraocular lens, visit www.acufocus.com.

Caution: Investigational Device. Limited by Federal (or United States) law to investigational use.