For Immediate Release
Contact: Silvana Guerci-Lena
Pascale Communications
silvana@pascalecommunications.com

AcuFocus Announces Submission of its U.S. Premarket Approval Application to the FDA for its IC-8® Small Aperture IOL

IRVINE, Calif., February 23, 2021 — AcuFocus, Inc., a privately held ophthalmic medical device company, announced today that it has submitted a Premarket Approval (PMA) application to the Food and Drug Administration (FDA) for its **IC-8** small aperture IOL.

The **IC-8** IOL is an aspheric monofocal lens that features an embedded filter with a small central aperture. Using wavefront-filtering, small aperture optics, the lens is designed to mitigate the harmful visual effects of unfocused peripheral light, allowing only central light rays to focus on the retina, and deliver continuous extended depth of focus.

CLINICAL TRIAL
Investigators evaluated the **IC-8** IOL in a prospective, multicenter, open-label, parallel-group, nonrandomized, examiner-masked, one-year clinical study to evaluate its safety and effectiveness. The company undertook the study to determine if the **IC-8** IOL, when implanted in conjunction with a monofocal or monofocal toric IOL in the fellow eye, would demonstrate better binocular intermediate and near visual acuity and similar distance visual acuity compared to bilateral aspheric monofocal or monofocal toric IOLs.

“The **IC-8** IOL is a first-of-its-kind presbyopia-correcting lens that is designed to deliver seamless visual acuity from near to far without the ‘blurry zones’ found in traditional lens designs,” said Magda Michna, PhD, Chief Global Clinical, Medical & Regulatory Affairs Officer, AcuFocus. “We are incredibly grateful to our investigators, their teams and the patients who participated in the study. Their commitment to the study integrity and follow-up timelines, especially during a global pandemic, helped us to achieve this critical milestone. We look forward to working with the FDA as they review our submission and results.”

A total of 343 study subjects and 110 control subjects were enrolled and followed for 12 months. Subjects in the study arm were implanted with an **IC-8** IOL in one eye and a control (monofocal or monofocal toric) IOL in their fellow eye. Control group subjects were bilaterally implanted with monofocal or monofocal toric IOLs.

“Participating in the **IC-8** IOL IDE study has been a wonderful opportunity for my patients and my practice,” said Elizabeth Yeu, MD, Virginia Eye Associates, Norfolk, VA. “The small aperture method of action is truly innovative and represents a real advancement in intraocular lens design. I am excited to have this lens in our practice as I believe it will fill a significant gap in our IOL options for patients.”

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ABOUT ACUFOCUS

AcuFocus, Inc., is a privately held ophthalmic medical device company that delivers breakthrough small aperture intraocular products to address diverse unmet needs and help patients achieve their best personal vision. The **IC-8** IOL received CE mark in 2015 and is available in select markets across Europe and Asia. AcuFocus is based in Irvine, Calif. For additional information about the **IC-8** IOL, visit www.acufocus.com.

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