For Immediate Release
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AcuFocus Completes Study Enrollment for U.S. IDE Clinical Trial of IC-8® Lens

IRVINE, Calif. – (June 14, 2019) – AcuFocus, Inc., a privately-held ophthalmic medical device company, announced today that it has completed enrollment in its pivotal U.S. Investigational Device Exemption (IDE) study of the company's **IC-8** small aperture intraocular lens (IOL) for patients with cataracts.

FDA granted approval of the company's IDE on November 21, 2018, and the Investigational Review Board approved the study just 5 hours later. With the first patient being enrolled 13 days after the approval, the **IC-8** IOL treatment arm of the study was enrolled in 6 months and the full study enrollment was completed in just over 7 months.

"Typically, a study like this would take up to 12 months to fully enroll, which is a testament to both the high-quality investigational team and the excitement for this lens technology," said Al Waterhouse, AcuFocus President and Chief Executive Officer. "The study is on track with our projected timeline, which puts us on pace for potential US market entry around Q4 2020/ Q1 2021."

A first-of-its-kind technology for cataract patients, the AcuFocus **IC-8** IOL is a clear monofocal lens with an embedded mini-ring or pinhole in the center. This proprietary lens design is intended to increase a patient's natural range of vision by extending the focus of light rays that enter the eye.

"Running a successful clinical trial depends on all participants - from the sponsor to the investigational sites - taking their role seriously and executing with high standards and focus," said Magda Michna, PhD, AcuFocus Chief Global Clinical and Regulatory Affairs Officer. "I couldn't be more pleased with the team and their efforts to meet the aggressive enrollment challenge we set forth."

The 12-month prospective, multicenter, non-randomized case control clinical trial will evaluate the improvement in vision achieved at all distances with the **IC-8** IOL when compared with traditional monofocal IOLs. Bilateral cataract patients assigned to the study group received contralateral implantation with an **IC-8** IOL and a monofocal or monofocal toric IOL and those assigned to the control group received bilateral monofocal or monofocal toric IOLs.

"The **IC-8** IOL is a real advancement in the field of IOL optics. My team and I have been hearing from my international colleagues about their results with the lens for a couple years now and we are just delighted with our experience to date," said Vance Thompson, MD, a clinical investigator for the trial. "Being a part of the team to evaluate this lens in the United States is truly an honor." Dr. Thompson is director of refractive surgery for Vance Thompson Vision in Sioux Falls, South Dakota.

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.