AcuFocus Announces FDA Approval for the IC-8® Apthera™ Intraocular Lens, the First and Only Small Aperture Lens for Cataract Surgery

- The **Apthera** extended depth of focus IOL uses proprietary small aperture technology to filter out peripheral defocused light, allowing only focused light to reach the retina.
- Results from the U.S. pivotal trial showed **Apthera** IOL subjects achieved statistically superior uncorrected intermediate and near vision, and equivalent distance vision and contrast sensitivity compared to control subjects.
- The number of people in the U.S. with a cataract, a clouding of the normally clear lens of the eye, is expected to double from 24.4 million to about 50 million by 2050.[1]

IRVINE, Calif., July 25, 2022 — AcuFocus, Inc., a privately held ophthalmic medical device company, today announced U.S. Food and Drug Administration (FDA) approval for its breakthrough **IC-8®** **Apthera™** intraocular lens (IOL) for the treatment of cataracts. The **Apthera** IOL is the first and only non-toric extended depth of focus IOL approved for the 82% of cataract patients who have as much as 1.5 diopters (D) of corneal astigmatism.[2]

"We are delighted to receive FDA approval for our first-of-its-kind **Apthera** IOL," said Al Waterhouse, president and chief executive officer for AcuFocus. "The **Apthera** IOL represents several firsts for surgeons and patients: the first small aperture IOL to receive FDA approval, the first lens indicated for implantation with a monofocal or monofocal toric IOL in the fellow eye, the first extended depth of focus lens indicated for monovision, and the first non-toric IOL indicated for cataract patients with low amounts of corneal astigmatism."

Cataracts are a common condition affecting an estimated 24 million people in the United States. Cataracts can only be treated with surgery in which the cloudy natural lens is removed and an artificial lens, or IOL, is implanted.[1] Most patients receive a monofocal IOL at the time of cataract surgery. While monofocal lenses provide excellent distance vision, objects up close remain blurry. Other available presbyopia-correcting lens designs have complex optics that split, shift, or stretch light to provide clear vision at more than one discrete focal point. In contrast, the **Apthera** IOL, with its proprietary small aperture technology, seamlessly provides excellent distance vision as well as clear intermediate and near vision, effectively mitigating the effects of presbyopia.

"The **Apthera** IOL is the first lens design, with its embedded **FilterRing**™ component, to mitigate the effects of presbyopia by simply filtering out peripheral defocused and aberrated light that degrades image quality. This allows central focused light to be delivered to the retina," said Vance Thompson, MD of Vance Thompson Vision, Sioux Falls, South Dakota. "This novel mechanism of action provides patients with continuous range of vision from far through intermediate and near, even if they have as much as 1.5 D of corneal astigmatism."

The FDA approval of the **Apthera** IOL is based on data from the U.S. Investigational Device Exemption study that evaluated the safety and effectiveness of the **Apthera** IOL implanted in one eye and a monofocal or monofocal toric IOL implanted in the fellow eye. A total of 453 subjects were enrolled and followed for 12 months. Outcomes for the **Apthera** IOL group (n=343) were compared to a control group (n=110) receiving a monofocal or monofocal toric IOL in both eyes. **Apthera** IOL treated eyes maintained 2 D of extended depth of focus and demonstrated 0.91 D of additional range of vision benefit over monofocal IOL eyes at 0.2 logMAR threshold, exceeding the 0.50 D ANSI criterion for extended depth of focus IOLs. **Apthera** IOL subjects achieved equivalent uncorrected distance vision and statistically superior intermediate and near vision compared to control subjects. **Apthera** IOL subjects also achieved comparable binocular contrast sensitivity to control subjects in both photopic and mesopic conditions, a first reported for an extended depth of focus lens.

"As one of the clinical investigators for the **Apthera** IOL, I saw firsthand how the unique optics work, and I can't wait to add it to my practice," said Elizabeth Yeu, MD of Virginia Eye Consultants, Norfolk, Virginia. "The **Apthera** IOL is unlike any lens we have had before. I believe it will fill a significant gap in our IOL armamentarium allowing every cataract surgeon to meaningfully expand their treatment options for patients."
The company plans to begin with a limited commercial release of the **Apthera** IOL in the U.S. in the fall of 2022.

ABOUT ASTIGMATISM

Astigmatism is a common eye condition that causes blurry far and/or near vision.[3] In a normal eye, the cornea (clear front part of the eye) has a round shape and allows the light rays coming into the eye to focus on a single point on the back of the eye (retina) to form a clear image. With astigmatism, the cornea has an oval shape and, as a result, the light rays do not focus at the same point on the retina. This may cause some parts of a viewed object to be unclear and may also lead to eye discomfort and headaches.

ABOUT THE **IC-8® APTHERA™** IOL

The **IC-8 Apthera** IOL is a wavefront-filtering intraocular lens for unilateral implantation in patients who have as much as 1.5 D of corneal astigmatism in the implanted eye. This IOL, compared to a monofocal or monofocal toric IOL, provides an extended range of vision from distance through near.
The **Apthera** IOL is the first extended depth of focus lens indicated for monovision.

As with any cataract surgery, risks of complications exist whether or not the IOL is implanted. The complications of IOL implantation surgery range from minor side effects (usually temporary) to serious complications. Patients with a history of previous illnesses or disorders of the eye may have a higher risk of complications. Patients with a history of retinal disease or those predisposed to retinal disease must not be implanted with the IOL. As with other extended depth of focus IOLs, further surgical treatment (such as IOL replacement for a different lens) may be needed after implantation of the IOL.
A full list of benefits and risks associated with the **IC-8 Apthera** IOL will be available in the Directions For Use and the Patient Information Brochure.

ABOUT ACUFOCUS

AcuFocus, Inc., is a privately held ophthalmic medical device company that delivers breakthrough small-aperture intraocular products to address diverse unmet needs in eye care and help patients achieve their best personal vision. The **IC-8® Apthera™** IOL (known as the IC-8 IOL in global markets) is approved in the United States for the treatment of cataract patients. The lens received CE mark in 2015 and is available in Australia, New Zealand, Singapore, and select markets across Europe. AcuFocus is based in Irvine, California. For more information about AcuFocus, visit www.acufocus.com and follow @AcuFocus on LinkedIn, Facebook, and Instagram and @AcuFocusInc on Twitter.

Sources:
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3. American Academy of Ophthalmology. https://www.aao.org/eye-health/diseases/what-is-astigmatism. July 18, 2022.