Evaluate Vantage

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US Kamra exposure limited after mixed panel vote

Elizabeth Cairns

AcuFocus's Kamra intraocular implant is approved in over 50 countries, but the US is not one of them. Following a mixed adcom vote last week this situation looks unlikely to change.

With a similar, rival product – ReVision Optics' Raindrop – in a pivotal US trial, AcuFocus might have missed its chance to get the US market to itself. AcuFocus has received investment from Medtronic among others, but ReVision counts Johnson & Johnson among its backers. Perhaps J&J will prove to have sharper vision than Medtronic when it comes to spotting potential.

The FDA's Ophthalmic Devices Panel was happy with the device's ability to improve near vision in patients with presbyopia, seven of the eight voting in its favour, but unconvinced on its safety; a deadlock was broken by a ninth vote against its safety from the chairperson.

The overall risk-benefit vote went in favour of the implant, but at four to three with one abstention it was hardly a resounding victory.

Complaints

The ring-shaped Kamra implant is placed in front of the iris and reduces the aperture of the eye in order to improve patients' near vision without compromising their distance sight (*Event – Panel to focus narrowly on corneal implant, May 19, 2014*). It was CE marked in 2009 and AcuFocus says that nearly 20,000 Kamras have been implanted outside the US.

But the FDA said in briefing documents that these ex-US implants had yielded 815 complaints; these included 362 patients who had to have their implants removed and a further 28 who required a second surgery.

It is not inevitable that the FDA will turn the device down but the agency is a stickler for safety and a demand for another trial is the likeliest outcome. And this could allow ReVision's Raindrop to streak past Kamra.

The devices work in different ways: Raindrop is a clear hydrogel resembling a tiny contact lens – it is 2mm in diameter – placed above the centre of the pupil, whereas Kamra is an opaque ring implanted in front of the iris to reduce the aperture of the eye. But they are designed for the same indication and compete with one another in Europe.

There is a third competitor in the EU: the Flexivue Microlens sold by Presbia. A US phase III trial of this lens is currently recruiting but is not scheduled to report until 2019, so Raindrop is the main threat to AcuFocus for now.

Raindrop's pivotal US trial has a completion date of May 2015 according to clinicaltrials.gov; if AcuFocus is forced to conduct an additional trial of similar scope to ReVision's, it could fall behind. AcuFocus needs the FDA to put is safety fears aside and approve Kamra despite the negative safety vote – and that would mean the FDA acting uncharacteristically.

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com or follow @LizEPVantage on Twitter