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Presbia sees its way to market

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Interim results for the pivotal US trial of Presbia's implantable lens look pretty good, suggesting that the company's Flexivue Microlens might meet with FDA approval when the final module of the PMA is submitted in the fourth quarter of this year. Presbia's shares closed up 7% on Nasdaq on Friday.

The commercial future of the device is uncertain. For a start two other implants designed to correct long sight are already approved in the US, and with the Microlens's approval not likely to happen before autumn 2018 they will have been able to entrench their positions. And it is still not clear how popular devices like this will be. Laser surgery for short sight is a large market, but patients with long sight only need to wear reading glasses some of the time. The appeal of surgical correction here could be more limited.

So far in the Microlens's pivotal trial 421 patients have undergone implantation of the device. It is implanted in only one of the patient's eyes – that with worse presbyopia.

Near and far

Interim data disclosed in an SEC filing suggest that, at 18 months, patients gained an average of five lines of uncorrected near visual acuity – the ability to see close objects without glasses – in treated eyes. For comparison, the first presbyopia implant approved in the US, Acufocus's Kamra device, improved uncorrected near visual acuity by an average of three lines 12 months after implantation.

The primary endpoint of the Microlens pivotal trial is uncorrected near visual acuity at 40cm of 20/40 or better in the operated eyes two years post-implant, so the final cut of the data will come in six months or so. The interim results show that at 18 months average uncorrected near visual acuity in the treated eye was 20/25 – better than 20/40.

In the pivotal Microlens trial, 82% of the patients achieved 20/40 or better uncorrected distance vision in treated eyes, and there was little change in binocular uncorrected distance vision from baseline. This is important since correcting the more long-sighted eye could in theory worsen the patients' distance vision. So far the Microlens seems to have avoided this.

Rivals

Acufocus's rival Kamra implant was approved in the US in April 2015 despite an FDA adcom giving it a rough ride (*US Kamra exposure limited after mixed panel vote, June 9, 2014*). It was joined by a second device, Revision Optics' Raindrop, last June.

Analysts from Jefferies note that the Raindrop's approval – awarded without an adcom being convened – was based on data including a five-line improvement in visual acuity and no loss in binocular distance vision. If Presbia's device can achieve similar gains out to the two-year time point it seems unlikely that the FDA will deny its approval on grounds of lack of efficacy.

And given that Kamra was approved despite a less than flawless safety record – high rates of explants were noted by the FDA panel – it might have a lowish bar to clear here as well.

US approval of the Microlens is expected in the second half of next year. The device is CE marked and sold in other markets including South Korea, but the company only recorded sales of $14,000 in 2016. Perhaps data from the pivotal US study, when they emerge, will contribute to increased usage of the Microlens outside the US. Certainly the sellside expects revenues to increase sharply in future: *EvaluateMedTech*'s consensus forecasts put sales of the device at $227m in 2022.

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