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Shooting Staar's implantable lens gets reluctant yes from adcom

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No members of the FDA's ophthalmic devices panel voted against Staar Surgical's Visian toric implanted Collamer lens (TICL) when it came to risk-benefit, but, with three of the nine members abstaining, the vote was still not a slam-dunk.

The company's stock had not been expected to move, with some analysts suggesting that a positive panel vote and indeed US approval itself were already accounted for in the price. But the panel vote, lukewarm though it was, prompted Canaccord Genuity to upgrade the stock from a hold to a buy, and investors followed that advice. Starr's shares are now worth $18.06, an 18% jump from their close on Friday.

Protocol violations

The panel was largely in agreement that the lens is effective, seven voting in favour with one against and one abstaining. On safety the vote was more equivocal, with five ayes, one no and three abstentions.

The 124-patient clinical trial examined by the panel showed that 82% of the eyes implanted with the Visian TICL had at 20/20 vision, and 54% of the eyes were 20/16 or better. But questions were raised over the study's rigour, according to the FDA's briefing documents. There were a number of lapses from the protocol, including the implantation of "a large number" of TICLs that were of different sizes or powers to those specified in the trial's protocol.

If approved, the product would become the first implanted lens that is both toric – capable of treating astigmatism – and phakic – not requiring the removal of the patient's native lens (*Event – Staar hopes lens will TICL adcom's fancy, February 10, 2014*). But if the FDA does say yes it will surely impose conditions, chief among which will be a postmarketing trial.

If there is little question over the need for a postmarketing trial, there is at least a discussion to be had about its design – whether a comparator group is necessary, for instance. The FDA will doubtless keep a close watch on the manner in which such a study is conducted.

Worth more

The TICL's forerunner, the non-toric Visian ICL, was approved by the FDA in December 2005 as a treatment for myopia and went on sale the following year. Comparing the two products in ex-US markets gives an indication of how much Staar stands to gain from US approval: in these 60-plus countries the TICL accounts for around 40% of the units but 50% of the revenue.

The product is thus worth more to Staar than the ICL, and the final indication for which the FDA clears the device is of great importance to the company. Staar is seeking approval for use in adults aged 21-45 with particular degrees of myopia or astigmatism; any restriction on age or the degree of visual impairment a patient will need to qualify for the lens could have meaningful consequences for the company's sales.

Staar and its enthusiastic new investors must hope that when the FDA comes to make its decision it concludes that the need for an implanted lens to treat myopic astigmatism outweighs any trial protocol concerns.

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