ESC 2019 – Amarin hopes for guideline boost despite regulatory delay

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Amarin is plugging a change in ESC guidelines to include Vascepa, but with the product’s regulatory fate undecided how much difference will this make to sales?

Amarin’s stock is down 16% since the news of a US approval delay that took the markets by surprise, but the company is still trying to look on the bright side.

The group is today making much of new European Society of Cardiology guidelines specifically recommending its fish oil product, Vascepa, but the question is how influential the guidelines will be while Vascepa is still awaiting decisions from regulators on its broad approval. This is even more relevant in Europe, where the product is not yet available for any use.

Seeking expanded approval

In the US Vascepa is indicated for patients with severe hypertriglyceridaemia, defined as levels of over 500mg/dl or greater. Amarin is seeking expanded approval for the reduction of cardiovascular risk in patients with statin-managed LDL-C cholesterol, but persistent elevated triglycerides, based on data from the Reduce-It trial.

Such a label change would increase Vascepa’s market from around four million US patients currently, to around 75 million. Meanwhile, the company plans to file Vascepa in Europe for reducing cardiovascular events by the end of 2019.

Since Reduce-It was declared a hit around a year ago forecasts for Vascepa have shot up, according to EvaluatePharma sellside consensus.

While much is riding on the FDA’s decision, Vascepa sales are already ticking up, presumably bolstered by off-label use in the US.
Dr Deepak Bhatt of the Brigham and Women's Hospital in Boston, who receives funding from Amarin and led the Reduce-It study, said the increase in Vascepa use did not surprise him. “Reduce-It put triglycerides back on the map in a big way,” he told Vantage at the ESC.

He added that the strength of clinical data was probably top of doctors’ list of priorities when deciding whether to prescribe a medication, even off-label. “Second, they want to see guideline endorsement; then, probably third on the list of priorities, is what are the approved indications?”

He did concede that there were still doctors who would want to see formal FDA approval before prescribing. And his words should probably be taken with a pinch of salt given his links with Amarin.

Impact?
Specifically, the ESC recommends that icosapent ethyl, the active ingredient of Vascepa, should be considered in patients with triglyceride levels of 135-499mg/dl despite statin treatment.

It is doubtful that the new guidelines will have a big impact in Europe, at least while Vascepa is not available there, and in the US it will be a while before any effect is seen. But the American Diabetes Association also backed Vascepa in a March 2019 guideline update, which could have already have helped sales.

Amarin’s stock, which rose as much as 3% this morning, is unlikely to return to the highs it has experienced this year until Vascepa’s fate in the US becomes clear. The product had been due an approval decision by September 27, but the FDA’s scheduling of an advisory committee meeting in November likely delayed the verdict until December.

The ESC guidelines might give Amarin a boost, but a positive adcom and broader approval are what investors are really waiting for.