

## Amarin surges as hopes for heart drug soar



[Amy Brown](#)

Hopes were already pretty high that Amarin would repeat its first phase III success with triglyceride lowering tablet, AMR101, and the outcome was much better. Data from a second pivotal study has smashed expectations held not only by optimistic followers, but also the company itself, sending its shares soaring 75% in early trade to \$15.

The omega-3 product was not only more effective than expected at cutting patients' triglyceride levels, it also showed a surprise reduction in LDL or "bad" cholesterol – an impressive result considering these patients were already on statins. These data confirm the drug's potential in a huge group of patients ill-served by current therapies and raises hopes it will pass the ultimate test – helping prevent cardiovascular events and death. Amarin's status as a prime takeover target has received a huge boost from these results.

### Where the riches lie

Heart attacks and strokes are still seen among patients who have successfully lowered LDL levels with statins – so targeting elevated triglyceride levels is believed to bring further benefits. Other than fibrates, which have tolerability issues, few options exist to do this, and it is this patient population that Amarin was targeting with this study.

The results presented today, from the Anchor trial, recruited 702 patients on statins with high triglycerides – judged to be between 200mg/dL and 500mg/dL. This is a distinct patient group from the previous study, Marine, which included patients with very high triglycerides – above 500mg/dL.

AMR101's main competitor, Lovaza, is only approved in the Marine patient group, largely because it is also associated with an elevation of LDL levels – an unacceptable side effect for people at a lower overall cardiac risk. In the Marine study, AMR101 showed similar efficacy to Lovaza in lowering triglycerides but crucially showed no impact on LDL ([Amarin soars on good news from Marine biologists on AMR101, November 29, 2010](#)).

But with no real competition in the Anchor population, this is where the riches lie. AMR101 needed to show strong triglyceride lowering, but more crucial was the LDL impact, and it succeeded on all counts.

### Larger population

The trial's primary endpoint – the percentage change in triglyceride levels from baseline compared to placebo after twelve weeks – was met by both 4g and 2g doses, with median placebo-adjusted reductions in triglyceride levels of 21.5% and 10.1% respectively. Even greater reductions were seen with higher potency statin regimens.

The drug not only met the FDA's LDL impact criteria, it actually showed an incremental benefit, with the 4mg dose showing a significant 6.2% reduction versus placebo, and a non-significant 3.6% reduction for the lower dose.

All secondary endpoints, which measured other lipid and inflammatory markers, were also met, while the safety profile was similar to placebo.

"We can now reach a population 10 times larger than Lovaza," said Joe Anderson, a non-executive director of Amarin and partner at Abingworth, the venture capital firm that led Amarin's \$70m fundraising in 2009.

"We were simply trying to show cholesterol neutrality, what we've shown is that there is a benefit, bringing cholesterol down further than with a statin on its own. That potentially changes the whole prescribing dynamic."

Although it is early days, Mr Anderson believes the potential exists for doctors to be able to spare higher statin doses by using AMR101, and for the drug to become an important add on to statin therapy in certain patients.

### Ultimate outcome

The ultimate proof of AMR101's potential will come with an outcome study that the FDA has already said will

be required for approval of the drug in the Anchor population. The study must be “substantially underway” at the time of filing, and is likely to include up to 9,000 patients and take five years.

The Anchor results raise the chance that this study will be a success, and show AMR101 is cardioprotective. With this rising chance comes rising valuation – the company has already said it believes the Marine population alone has billion dollar potential – the Anchor population is ten times as big.

Before these results were released analysts had pencilled in sales of \$2.26bn by 2016, according to *EvaluatePharma*, and that number will now rise. Hence the spectacular surge in Amarin’s valuation today – currently standing at \$1.8bn.

The company has made no secret of the fact that a lot of parties are already interested, and with this data more are likely to be beating on the door. The prospect of a multi-billion dollar drug potentially 18 months from the market will be hugely tempting for a lot of companies. Amarin is pushing on alone for now, but an offer it cannot refuse could well be on the way.

<b>Trial ID</b>	NCT01047683 (Marine)	NCT01047501 (Anchor)
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