



August 31, 2016

## **Amarin Randomizes Final Patient into REDUCE-IT Cardiovascular Outcomes Study of Vascepa**

### **8,175 Individual Patients Randomized and All Global Sites Closed to Enrollment**

BEDMINSTER, N.J. and DUBLIN, Ireland, Aug. 31, 2016 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) announced that randomization of patients into the REDUCE-IT cardiovascular outcomes study has been completed with 8,175 individual patients randomized, in accordance with the study protocol, on a 1:1 basis between Vascepa<sup>®</sup> (icosapent ethyl) and placebo, slightly exceeding the 8,000 patients targeted for the trial.

The REDUCE-IT study is evaluating whether treatment with Vascepa reduces cardiovascular events in patients who despite stabilized statin therapy have elevated triglyceride levels and other cardiovascular risk factors. Amarin closed enrollment at all global clinical sites in June 2016. Before randomization, patients enrolled in the trial went through a protocol-specified monitoring period to ensure that their LDL-cholesterol was well-controlled on statin therapy and that they were washed out of exclusionary non-statin lipid modifying therapies.

"We are pleased to have completed the randomization of all patients into REDUCE-IT," said Steven Ketchum, Ph.D., president of R&D and chief scientific officer of Amarin. "Our remaining focus is on ensuring that this important study continues to progress as planned. While we were confident in the design of the study at the target of 8,000 patients, the yield of additional patients from the screening and randomization process is consistent with our efforts throughout this study to ensure that the trial results are robust."

Amarin continues to expect the onset of the final primary cardiovascular event to occur in the second half of 2017 with publication of trial results likely in 2018. An independent Data Monitoring Committee (DMC) is expected to complete a protocol pre-specified interim efficacy and safety analysis after approximately 60% of the target aggregate primary cardiovascular events have occurred within the study. This interim analysis is most likely to occur in September 2016. A second interim efficacy and safety analysis with approximately 80% of the primary cardiovascular events is expected in mid-2017.

While it is possible that the study could terminate early for overwhelming efficacy at either the 60% or 80% interim analysis, guidelines for the independent DMC to recommend stopping the study for overwhelming efficacy require that the study achieve a high level of statistical significance on the primary endpoint and generate other robust findings including on certain, pre-specified secondary outcome measures to support an overall favorable benefit/risk profile. Given the high threshold of overwhelming efficacy required for a DMC to recommend an early stop to a cardiovascular outcomes trial like REDUCE-IT, Amarin continues to expect that the DMC's interim analysis will result in a recommendation to continue the REDUCE-IT study as planned. REDUCE-IT is designed for Amarin to remain blinded to results of the study until after the study is stopped at either of the interim analyses or for the final analysis.

### **About REDUCE-IT**

REDUCE-IT is a global Phase 3, randomized, multicenter, double-blind, placebo-controlled study designed to evaluate whether treatment with Vascepa reduces cardiovascular events in patients who have persistently elevated triglyceride levels despite stabilized statin therapy and other cardiovascular risk factors. The primary endpoint of the study is the time to the first occurrence of the composite endpoint of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or hospitalization for unstable angina. Secondary endpoints include time to event analyses of components of the primary endpoint.

Additional information on the REDUCE-IT trial and Amarin's other clinical studies of Vascepa can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About Vascepa<sup>®</sup> (icosapent ethyl) capsules**

Vascepa<sup>®</sup> (icosapent ethyl) capsules are a single-molecule prescription product consisting of 1 gram of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single

molecule active ingredient. Vascepa is known in scientific literature as AMR101.

### FDA-approved Indication and Usage

- 1 Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.
- 1 The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

### Important Safety Information for Vascepa

- 1 Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- 1 Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- 1 The most common reported adverse reaction (incidence  $> 2\%$  and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction  $> 3\%$  and greater than placebo.
- 1 Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
  
- 1 In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
  
- 1 Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.
- 1 Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT [WWW.VASCEPA.COM](http://WWW.VASCEPA.COM).

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. Nothing in this press release should be construed as promoting the use of Vascepa in any indication that has not been approved by the FDA.

### **About Amarin**

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Amarin's clinical program includes a commitment to the ongoing REDUCE-IT cardiovascular outcomes study. Vascepa<sup>®</sup> (icosapent ethyl), Amarin's first FDA-approved product, is a highly-pure, EPA-only, omega-3 fatty acid product available by prescription. For more information about Vascepa, visit [www.vascepa.com](http://www.vascepa.com). For more information about Amarin, visit [www.amarincorp.com](http://www.amarincorp.com).

### **Forward-looking statements**

This press release contains forward-looking statements, including statements about the company's confidence in the design of REDUCE-IT and efforts to help ensure robust results; the timing of cardiovascular events in REDUCE-IT and the timing of occurrence, assessment and publication of interim and final trial results from REDUCE-IT; and expected outcomes from the REDUCE-IT DMC's interim analysis. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or expected herein include uncertainties associated generally with complex clinical trials like REDUCE-IT and research and development and clinical trial risk generally; differing views on interpretation of clinical trial results; and reliance on third parties. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Quarterly Report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

### **Availability of other information about Amarin**

Investors and others should note that we communicate with our investors and the public using our company website ([www.amarincorp.com](http://www.amarincorp.com)), our investor relations website (<http://www.amarincorp.com/investor-splash.html>), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public

conference calls and webcasts. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Amarin to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

Amarin Contact Information:

Investor Relations:

Kathryn McNeil

Investor Relations and Corporate Communications

Amarin Corporation plc

In U.S.: +1 (908) 719-1315

[investor.relations@amarincorp.com](mailto:investor.relations@amarincorp.com)

Lee M. Stern

Trout Group

In U.S.: +1 (646) 378-2922

[lstern@troutgroup.com](mailto:lstern@troutgroup.com)

Media Inquiries:

Ovidio Torres

Finn Partners

In U.S.: +1 (312) 329 3911

[ovidio.torres@finnpartners.com](mailto:ovidio.torres@finnpartners.com)

 Primary Logo

Source: Amarin Corporation plc

News Provided by Acquire Media