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Amarin's REDUCE-IT Cardiovascular Outcomes Study of Vascepa to Continue as Planned at Recommendation of Independent Data Monitoring Committee

BEDMINSTER, N.J. and DUBLIN, Ireland, Sept. 12, 2016 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) announced that, as expected, the independent data monitoring committee (DMC) has completed its review of the first pre-specified interim efficacy analysis for the REDUCE-IT cardiovascular outcomes study and has recommended that the trial continue as planned without modification. The 8,175-patient outcomes study is evaluating whether treatment with Vascepa® (icosapent ethyl) reduces cardiovascular events in patients who despite stabilized statin therapy have elevated triglyceride levels and other cardiovascular risk factors.

In accordance with the study protocol, the first interim efficacy analysis was performed after adjudication of approximately 60% of the target 1,612 aggregate primary cardiovascular events occurred within the study. Preparations for a second planned interim efficacy analysis will be triggered by the onset of approximately 80% of the target aggregate number of primary cardiovascular events. Amarin anticipates that the onset of approximately 80% of events will occur in the first half of 2017, with the second pre-specified interim efficacy analysis and review by the DMC expected around mid-2017. Amarin will remain blinded to results of the study until after the study is stopped and the database is locked at either the second interim analysis or at the final analysis.

The DMC's recommendation to continue as planned also reflects its review of all available safety data. In accordance with the study protocol and DMC charter, safety reviews have been performed multiple times each year since REDUCE-IT began in December 2011, and more than 23,000 patient years of study have been accumulated to date in the ongoing REDUCE-IT study. The review and recommendation of the DMC was made independently. Neither Amarin nor the FDA has reviewed the interim clinical results and neither participated in the DMC's closed session deliberation.

"We have accepted the independent DMC's recommendation, and we are pleased that REDUCE-IT continues as planned. We continue to anticipate that accumulation of additional cardiovascular events will add further robustness to the results of this important study which is the first outcomes study ever to evaluate if the addition of pure EPA Vascepa to statin therapy confers a meaningful reduction in the occurrence of major cardiovascular events in patients with persistent elevated triglycerides and other cardiovascular risk factors," said Steven Ketchum, Ph.D., president of R&D and chief scientific officer of Amarin. "We remain confident that the REDUCE-IT study is positioned for success based on our extensive review of existing data from clinical, epidemiologic and genetic studies, and we look forward to the study's anticipated completion. We continue to expect the onset of the final primary cardiovascular event to occur in the second half of 2017 with the publication of results anticipated in 2018."

Residual Cardiovascular Risk in Statin-Treated Patients

Cardiovascular disease remains the leading cause of death in the United States, with the estimated costs of treating heart attacks, strokes and other cardiovascular disease manifestations exceeding $300 billion annually.[1] In the United States, more than 35 million patients are treated with statins for the primary and secondary prevention of atherosclerotic cardiovascular events, including heart attacks and stroke.[2,3] Despite the demonstrated clinical benefits of lowering bad cholesterol (LDL-C) with statins, 60% to 75% residual cardiovascular risk remains for statin-treated patients.[4,5,6] Vascepa is being studied in REDUCE-IT as an add-on to statin therapy to further reduce cardiovascular risk, not as a replacement for statin therapy.

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 despite stabilized statin therapy have elevated triglyceride levels 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 (heart attack), nonfatal stroke, coronary revascularization, or hospitalization for unstable angina. Secondary endpoints include time to event analyses of components of the primary endpoint. The study is being conducted under a special protocol assessment agreement with the FDA.

Additional information on the REDUCE-IT trial and Amarin's other clinical studies of Vascepa can be found at

www.clinicaltrials.gov.

About Vascepa® (icosapent ethyl) capsules

Vascepa® (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.

[1] Mozaffarian et al. Circulation. 2016;133: e43, e184.

[2] NCHS Data Brief No. 177, December 2014. Retrieved from http://www.cdc.gov/nchs/products/databriefs/db177.htm.

[3] U.S. Census Bureau. (2012). Age and Sex Composition in the United States: 2012. Retrieved from http://www.census.gov/population/age/data/2012comp.html

[4] Hobbs FD, et al. BMC Med. 2016;14:4.

[5] Cholesterol Treatment Trialists' (CTT) Collaboration, et al. Lancet. 2010;376(9753):1670-1681.

[6] Koenig W. J Am Coll Cardiol. 2008;51(17):1642-4.

FDA-approved Indication and Usage

- Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.
- 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

- Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- 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.
- Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.
- 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.

Vascepa has been approved for use by the FDA as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 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® (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. For more information about Amarin, visit www.amarincorp.com.

Forward-looking statements

This press release contains forward-looking statements, including statements about the anticipated timing of cardiovascular events in REDUCE-IT and the timing of occurrence, assessment and publication of interim and final trial results from REDUCE-IT; the company's expectations that accumulation of additional cardiovascular events will add further robustness to REDUCE-IT study results; and the company's confidence in REDUCE-IT being positioned for success based on review of existing data from clinical, epidemiologic and genetic studies. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. For example, statements related to the potential efficacy and therapeutic benefits of Vascepa have been subject to different interpretations on matters such as the potential clinical importance of lowering triglyceride levels in studied patients. Among the factors that could cause actual results to differ materially from those described or projected 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), 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.

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