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

Landmark Cardiovascular Outcomes Study On-Track for Completion in 2018

BEDMINSTER, N.J. and DUBLIN, Ireland, Aug. 14, 2017 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) announced that, as expected, the independent data monitoring committee (DMC) has completed its review of the scheduled pre-specified interim efficacy and safety analysis for the REDUCE-IT cardiovascular outcomes study and has recommended that the trial continue as planned without modification. Because REDUCE-IT is the first prospective clinical trial of any therapy in the large patient population studied, the bars for stopping this trial early for overwhelming efficacy were intentionally set high with the understanding that a more robust result, based on a larger number of cardiovascular events, could be obtained by the study continuing to completion. Results from the completed study are expected in Q2 or Q3 2018. The 8,175-patient outcomes study is evaluating whether treatment with Vascepa® (icosapent ethyl) reduces major adverse cardiovascular events in patients who despite stabilized statin therapy have elevated triglyceride levels and other cardiovascular risk factors.

In accordance with the study protocol, this interim efficacy analysis was performed after adjudication of approximately 80% of the target 1,612 aggregate primary cardiovascular events occurred within the study. Preparations for a final efficacy analysis will be triggered by the onset of approximately 100% of the target aggregate number of primary cardiovascular events. Amarin anticipates that the onset of approximately 100% of events will likely occur in early 2018. Amarin is intentionally blinded to the interim analysis data and will remain blinded to results of the study until after the study is stopped and the database is locked 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 30,000 patient years of study have been accumulated to date in the ongoing REDUCE-IT study.

The review and recommendation of the DMC at this interim look were made independently. Neither Amarin nor the FDA has reviewed the interim clinical results and neither participated in the DMC's closed session deliberation.

"We are pleased that we are nearing completion of the REDUCE-IT study and thank the independent DMC members for their diligence in overseeing this important study," said Steven Ketchum, Ph.D., president of R&D and chief scientific officer of Amarin. "This interim look provided important operational checks in preparation for study completion. We remain confident that the REDUCE-IT study is positioned for success based on our extensive review of the existing and continually increasing body of data from clinical, epidemiologic, genetic, and real-world evidence studies, and we are preparing for the study conclusion."

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 $550 billion annually.[1] In the United States, about 40 million patients are treated with statins for the primary and secondary prevention of atherosclerotic cardiovascular events, including heart attacks and stroke.[2] Despite the demonstrated clinical benefits of lowering bad cholesterol (LDL-C) with statins, 60% to 75% residual cardiovascular risk remains for statin-treated patients.[3] Vascepa is being studied in REDUCE-IT as an add-on to statin therapy in patients with persistent elevated triglycerides and other risk factors to further reduce cardiovascular risk, not as a replacement for statin therapy.

About Vascepa® (icosapent ethyl) capsules

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting 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. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in

relevant patient populations without raising LDL-cholesterol levels.

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 United States Food and Drug Administration (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.

Forward-looking statements

This press release contains forward-looking statements, including expectations for continued event rates, interim data review, results and related timing and announcements with respect to Amarin's REDUCE-IT cardiovascular outcomes study; expectations related to the final outcomes of the REDUCE-IT study and the anticipated successful completion of the REDUCE-IT study; and statements regarding the potential and therapeutic benefits of Vascepa. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in filings with the U.S. Securities and Exchange Commission, Amarin's ability to effectively develop and commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve increased market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that historical REDUCE-IT event rates may not be predictive of future results and related cost may increase beyond expectations; the risk that regulatory reviews may alter current expectations related thereto; the risk that future legal determinations and interactions with regulatory authorities may impact Vascepa marketing and sales rights and efforts; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for cardiovascular risk reduction; and the risk that patents may not be upheld in patent litigation. 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://investor.amarincorp.com), 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.

References

[1] AHA Heart and Stroke Statistics https://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_491543.pdf

[2] http://www.acsh.org/news/2015/12/04/cdc-study-reveals-that-too-few-americans-are-on-statins

[3] Libby P. J Am Coll Cardiol. 2005:46(7):1225-1228.

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