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## **Amarin Announces REDUCE-IT Cardiovascular Outcomes Study Final Patient Visits to Commence in March 2018**

### **On-Track to Report Clinical Results for this Potential Landmark Study Before the End of Q3 2018**

BEDMINSTER, N.J., and DUBLIN, Ireland, Dec. 19, 2017 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today announced REDUCE-IT cardiovascular outcomes study clinical sites have been instructed to begin scheduling patients for final study visits commencing March 1, 2018. Amarin confirmed it is on track to report top-line results from the first of its kind, potentially landmark, REDUCE-IT cardiovascular outcomes study before the end of Q3 2018. Amarin maintains its guidance that the onset of the targeted 1,612th primary major adverse cardiovascular event (MACE) in this study is projected to occur before the end of Q1 2018.

Amarin is excited that this important study of over 8,000 patients, which began in 2011, is nearing conclusion. The company looks forward to learning and reporting the results of this first ever prospective study of drug therapy to lower cardiovascular risk in patients who, despite controlled LDL-cholesterol, have elevated triglyceride levels and other cardiovascular risk factors. The REDUCE-IT study is being conducted at over 400 clinical sites in 11 countries. To facilitate a timely study wrap-up, Amarin has informed clinical sites that study completion is close at hand, and that they should begin to schedule patients for their final patient visit. During on-site final patient visits, clinical sites will confirm vital status, take a lipid panel and other blood measures, and complete each patient's physical examination and updated medical history record including any potential clinical events. This final patient visit process is consistent with prior cardiovascular outcomes studies for other drugs evaluating other indications for use, and consistent with the study design of the REDUCE-IT trial, which is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration.

"Scheduling final patient visits is an important step toward completion of the REDUCE-IT study," commented Dr. Steven Ketchum, Amarin senior vice president, president of R&D, and chief scientific officer. "We are very appreciative of the continued dedication of patients and clinical sites in this study. We believe the results of this study will provide valuable clinical and scientific information about the potential outcomes benefit of Vascepa and lead to better informed preventative care of patients at high cardiovascular risk. The results of recent real-world evidence studies presented at the annual scientific sessions of the American Heart Association in November 2017 provide us further evidence of the increased cardiovascular risk in patients with elevated triglyceride levels and optimism for the potential impact of the first of its kind REDUCE-IT study."

Amarin is intentionally blinded to the interim analysis data and will remain blinded to results of the study until after the study is completed and the database is locked. Final patient visits will be followed by adjudication of all newly reported cardiovascular events in the study, completing data entry for the now greater than 30,000 patient years of study in REDUCE-IT, and typical database quality control measures, known as cleaning. This will be followed by database lock and final efficacy and safety analyses, including analysis of the trial's primary endpoint of first MACE events in the study and the more than thirty pre-defined secondary and tertiary endpoints. Publication of the study design can be found at <https://doi.org/10.1002/clc.22692>. The lead author of this paper published in *Clinical Cardiology* was Deepak L. Bhatt, M.D., M.P.H., executive director of the Interventional Cardiovascular Programs at Brigham and Women's Hospital, professor of medicine, Harvard Medical School in Boston, Mass.

The timing of the announcement of the March 1, 2018 commencement of final patient visits in the REDUCE-IT study reflects projections of the onset of the targeted 1,612th primary MACE, and the practical reality that it requires time to effectively schedule thousands of patients in multiple countries to visit clinical sites in an orderly and timely manner. The estimate of timing of the onset of the 1,612th MACE event is based on actual adjudicated events from inception to date in the study. The projection of the number of MACE events that will ultimately be adjudicated as a primary event (first event for the patient within the duration of the study) is also based on historical data of adjudicated events within the REDUCE-IT study. Such projections are made by independent statisticians and reviewed by Amarin and the independent steering committee for the trial, all of whom are blinded. The study was designed to provide sufficient power to detect the anticipated result, regardless of whether the final number of primary MACE is slightly more or slightly fewer than 1,612 primary MACE.

#### **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 an ongoing outcomes study. Vascepa<sup>®</sup> (icosapent ethyl), Amarin's first FDA approved product, is a highly-pure, 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).

## About REDUCE-IT

Amarin's clinical development program for Vascepa includes a trial known as the REDUCE-IT cardiovascular outcomes study, an 8,175-patient study commenced in 2011. REDUCE-IT is the first multinational cardiovascular outcomes study evaluating the effect of prescription pure EPA therapy, or any triglyceride lowering therapy, as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, have elevated triglyceride levels (150-499 mg/dL). A large portion of the male and female patients enrolled in this outcomes study are anticipated to also be diagnosed with type 2 diabetes. As reported previously, Amarin expects that the onset of the target final primary cardiovascular event will be reached before the end of Q1 2018, with results announced before the end of Q3 2018.

Additional information on 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 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 ( $\geq 500$  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](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. 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 related to the anticipated timing of events and the evaluation thereof in the REDUCE-IT cardiovascular outcomes study and Amarin and study site participants' plans to collect, assess, process, and analyze data and make relevant determinations on the outcome of the study. These statements are not promises or guarantees of the anticipated timing of such events, the level of quality of the data and analyses or the potential for a favorable outcome from the ongoing REDUCE-IT cardiovascular outcomes trial. As disclosed in filings with the U.S. Securities and Exchange Commission, Amarin is substantially dependent on third parties for much of the relevant work described in this press release and 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 the aforementioned and other 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, data collection and assessment, clinical trials and related regulatory approvals; risks associated with reliance on third parties; 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 Amarin communicates with its investors and the public using the company website (<http://www.amarincorp.com/>), the 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 Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media, and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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