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Amarin's REDUCE-IT Cardiovascular Outcomes Study Reaches 90% Mark for Reported Primary Events

On Track for Patient Final Study Visits to Commence in March 2018

BEDMINSTER, N.J. and DUBLIN, Ireland, Jan. 23, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today announced that its REDUCE-IT cardiovascular outcomes study has reported and documented more than 90% of the targeted 1,612 primary major adverse cardiovascular events (MACE). The vast majority of these events have been confirmed (i.e., positively adjudicated as a patient's first on-study primary event) with some unable to be fully adjudicated per study protocol until after completion of the associated patients' final study visits. For this first of its kind, potentially landmark, REDUCE-IT cardiovascular outcomes study, Amarin confirmed that it is on track for onset of the targeted 1,612th event to occur before the end of Q1 2018. Patients are being scheduled for final study visits commencing March 1, 2018. Amarin maintains its guidance to report top-line results from the study before the end of Q3 2018.

"We are pleased to be nearing conclusion of this important study," commented Dr. Steven Ketchum, Amarin senior vice president, president of R&D, and chief scientific officer. "The timing of accumulated events in this study and the scheduling of final patient visits are two important steps towards learning the results of this study and understanding the extent to which Vascepa and the REDUCE-IT trial results can lead to better informed preventative care of patients at high cardiovascular risk."

Amarin is intentionally blinded to the results of the study and will remain blinded to such results until after the study is completed and the database is locked. Final patient visits will be followed by adjudication of newly reported cardiovascular events in the study, completing data entry for the greater than 33,000 patient years of study in REDUCE-IT, and typical database quality control measures, known as cleaning. This will be followed by the 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 analyses of 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 C*linical Cardiology* is 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 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. Vascepa® (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. For more information about Amarin visit 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 to announce top-line results of this important study before the end of Q3 2018. The REDUCE-IT trial is being conducted under a Special Protocol Assessment agreement with the U.S. Food

and Drug Administration.

Additional information on 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 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, known in scientific literature as AMR101, has been designated a new chemical entity by the FDA. 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. 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 statements related to the REDUCE-IT cardiovascular outcomes study including expectations for timing of last patient visits, continued event rates, results and the timing for related announcements of such events; expectations related to the sufficiency of statistical measures and protocols; expectations with respect to the successful completion of the REDUCE-IT study; and statements regarding the potential efficacy, safety 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 its filings with the U.S. Securities and Exchange Commission, Amarin's ability to effectively 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 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 related cost may increase beyond expectations; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for intended uses; the risk that patents may not be upheld in patent litigation and applications may not result in issued patents sufficient to protect the Vascepa franchise. 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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