March 1, 2018

# Amarin Announces Start of Final Clinical Site Visits in the REDUCE-IT Cardiovascular Outcomes Study

## Study Results Anticipated to be Released by End of Q3 2018

BEDMINSTER, N.J. and DUBLIN, Ireland, March 01, 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 final study-related visits have commenced for patients enrolled in its REDUCE-IT cardiovascular outcomes study. An important step in completion of this potentially landmark study is to have patients return to their clinical sites for final study data collection. Commencing final patient visits on March 1, 2018 is consistent with the company's estimated schedule of having results of this first of its kind study announced before the end of the third quarter of this year.

"We are excited that the REDUCE-IT trial is nearing completion and appreciative for the participation of patients and clinical sites in this important clinical study," commented Dr. Steven Ketchum, Amarin senior vice president, president of R&D, and chief scientific officer. "The commencement of final patient visits is a positive step towards completing this six-year, 8,175 patient study."

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 time to the first major adverse cardiovascular events (MACE) 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.

### 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 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.

**About Cardiovascular Disease**

Worldwide, cardiovascular disease (CVD) remains the #1 killer of men and women. In the United States CVD leads to one in every three deaths - one death approximately every 38 seconds - with annual treatment cost in excess of $500 billion.[1, 2]

Beyond the cardiovascular risk associated with LDL-C, genetic, epidemiologic, clinical and real-world data suggest that patients with elevated triglycerides (TG) (fats in the blood), and TG-rich lipoproteins, are at increased risk for cardiovascular disease. [3, 4, 5, 6]

Leading clinical investigations seeking to address cardiovascular risk reduction beyond lowering LDL-C focus on interrupting the atherosclerotic process (e.g., plaque formation and instability) by beneficially affecting other lipid, lipoprotein and inflammation biomarkers and cellular functions thought to be related to atherosclerosis and cardiovascular events.

**Forward-Looking Statements**

This press release contains forward-looking statements, including predictions and statements related to operational activities to be carried in connection with the REDUCE-IT cardiovascular outcomes study such as timing of last patient visits, adjudication of newly reported cardiovascular events, completion of data entry, typical database quality control measures, database lock and final efficacy and safety analyses, analysis of study results such as the trial's primary endpoint, pre-defined secondary and tertiary endpoints and timing for related announcements of such events. 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 projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for intended uses. 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 annual report on Form 10-K. 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.

**References**

[1] American Heart Association. 2018. Disease and Stroke Statistics-2018 Update.

[2] American Heart Association. 2017. Cardiovascular disease: A costly burden for America projections through 2035.

[3] Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. *Am J Cardiol*.

2016;118:138-145.

[4] Toth PP, Granowitz C, Hull M, et al. High triglycerides increase cardiovascular events, medical costs, and resource utilization in a real-world analysis of statin-treated patients with high cardiovascular risk and well-controlled low-density lipoprotein cholesterol [abstract]. *Circulation*. 2017;136(suppl 1):A15187.

[5] Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology. *Circ Res*. 2016;118:547-563.

[6] Nordestgaard BG, Varbo A. Triglycerides and cardiovascular disease. *Lancet.* 2014; 384: 626-635.

**Amarin Contact Information**

*Investor Relations:*
Elisabeth Schwartz
Investor Relations and Corporate Communications
Amarin Corporation plc
In U.S.: +1 (908) 719-1315
investor.relations@amarincorp.com

Lee M. Stern
Trout Group
In U.S.: +1 (646) 378-2992
lstern@troutgroup.com

*Media Inquiries:*
Kristie Kuhl
Finn Partners
In U.S.: +1 (212) 583-2791
Kristie.kuhl@finnpartners.com

Primary Logo

Source: Amarin Corporation plc