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Amarin Announces Expanded Research Relationships and Studies to Help Improve Cardiovascular Care

BEDMINSTER, N.J. and DUBLIN, Ireland, May 18, 2017 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, announced today three new studies it is coordinating with leading health organizations and physicians. These studies are described in abstracts presented this week at the National Lipid Association (NLA) 2017 Scientific Sessions in Philadelphia.

Two of the studies leverage real-world evidence (RWE):

- A study led by Peter Toth, M.D., Ph.D., Director, Preventive Cardiology, CGH Medical Center, Sterling, IL, determined that the use of RWE data from medical and pharmacy claims can provide strong insight into medication patterns, cardiovascular events, healthcare costs, and resource utilization in an at-risk population similar to the patients being studied in Amarin's REDUCE-IT outcomes study. This RWE study is presented in a poster (abstract #139) titled, "Baseline Characteristics of a Retrospective Claims Analysis of Cardiovascular Outcomes and Health Care Resource Utilization and Costs in High-Risk Statin-Treated Patients with Hypertriglyceridemia."

- In a study led by Gregory Nichols, Ph.D., from the Kaiser Permanente Center for Health Research, and in collaboration with Sergio Fazio, M.D., Ph.D., Director, Center for Preventive Cardiology, Oregon Health & Science University, Portland, OR, RWE data from a large integrated healthcare system determined that electronic health records (EHRs) may be an efficient tool for identifying and screening high-risk patients, such as those sought for evaluation in outcome studies. This study is presented in a poster (abstract #138) titled "The Potential of Electronic Health Record Data to Optimize Recruitment Efficiency in Cardiovascular Outcome Trials."

Both of these studies utilize large patient databases to better define and understand cardiovascular patient demographics and profiles in the real world, particularly in a population of statin-treated patients with dyslipidemia. Further study is planned using this RWE with emphasis on better understanding the increase in patient treatment costs associated with this at-risk population. These studies are intended to complement Amarin's ongoing REDUCE-IT cardiovascular outcomes study.

A third study will evaluate the reduction of coronary plaque using Vascepa® (icosapent ethyl). This study, titled EVAPORATE ("Effect of Icosapent Ethyl on Progression of Coronary Atherosclerosis in Patients with Elevated Triglycerides [200-499 mg/dL] on Statin Therapy"), will be led by Matthew J. Budoff, M.D., Professor, David Geffen School of Medicine at UCLA and program director of Cardiac CT at Harbor-UCLA Medical Center. EVAPORATE will be the first study to use MDCT to evaluate the effects of icosapent ethyl on plaque characteristics in patients with persistent high triglyceride (TG) levels. MDCT, multidetector computed tomography, is an advanced technology for diagnostic imaging. The EVAPORATE study will be presented as a poster (abstract #143).

"Amarin is pleased to be working with many leading physicians, academic centers and healthcare systems with a shared vision of finding ways to cost-effectively improve patient care," said Craig B. Granowitz, M.D., Ph.D., chief medical officer of Amarin. "These studies are intended to provide a deeper understanding of cardiovascular disease and its cost and treatment."

Amarin's commitment to advancing scientific knowledge and patient care is evidenced by the more than 30 scientific publications and abstracts sponsored in 2016. The costs of these new studies are included in the company's previously provided financial guidance for 2017.

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® (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 is known in scientific literature as AMR101.

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 results from real-world evidence studies, reduction of coronary plaque using Vascepa®, costs of research and development; expectations for 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 impact the current design of the REDUCE-IT study or cause a change in strategic direction with respect to continuation of the study; 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 anticipated 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.

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:

Ovidio Torres

Finn Partners

In U.S.: +1 (312) 329 3911

ovidio.torres@finnpartners.com

Primary Logo

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