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Real World Data Analysis Shows That Persistent Hypertriglyceridemia Despite Statin Therapy is Associated With Cardiovascular Risk

High Triglyceride Levels Associated with 30% Increased Risk of Myocardial Infarction & Coronary Revascularization and 13% Overall Increase in Major Adverse Cardiovascular Events

BEDMINSTER, N.J. and DUBLIN, Ireland, Nov. 14, 2017 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, announced data analysis orally presented today at the American Heart Association (AHA) 2017 Scientific Sessions in Anaheim, California. The oral presentation used real world evidence (RWE) as a basis for the analysis. This analysis of RWE is separate from and independent of the RWE analysis referenced in Amarin's press release on November 12, 2017.

The oral presentation, "Increased Cardiovascular Risk in Patients with Statin-Controlled LDL Cholesterol and Residual Hypertriglyceridemia," was done in collaboration with Gregory A. Nichols, PhD, from Kaiser Permanente Center for Health Research, and Sergio Fazio, MD, PhD, Director, Center for Preventive Cardiology, Oregon Health & Science University, Portland, OR. The study analyzed data from the Southern California and Northwest regions of Kaiser Permanente, one of America's leading health care providers and not-for-profit health plans. The patients selected had a diagnosis of atherosclerotic cardiovascular disease (ASCVD: myocardial infarction [MI], ischemic stroke, and peripheral artery disease) and had statin-controlled LDL cholesterol (LDL-C). The study concluded that during the study period, despite statin-controlled LDL-C levels, ASCVD events were greater among patients with ASCVD and high (200-499 mg/dL, n=2,361) vs. normal (< 150 mg/dL, n=14,454) triglyceride (TG) levels.

Over an average follow-up of 4.2 years, statin-treated ASCVD patients with persistent high TGs, as compared with the statin-treated normal TG group, were at increased risk of cardiovascular outcomes after multivariable adjustment as follows:

- 30% increased risk for myocardial infarction (95% CI 1.05-1.61)
- 30% increased risk for coronary revascularization (95% CI 1.08-1.57)
- 13% increased risk for the composite outcome (95% CI 1.02-1.26)

Composite outcome = nonfatal MI, nonfatal stroke, coronary revascularization, unstable angina, or all-cause mortality

Risk of all-cause mortality, which was the largest contributor to the composite outcome, was similar between TG groups. This study analyzed health data of real-world patients and was not a prospective analysis of medical intervention. Mortality attributable to cardiovascular conditions was not evaluated separately from all-cause mortality for either of the TG groups.

The study authors were Gregory A. Nichols, Kaiser Permanente Northwest Center for Health Research, Portland, OR; Sephy Philip, Craig B. Granowitz, Amarin Pharma, Inc, Bedminster, NJ; Kristi Reynolds, Kaiser Permanente Southern California, Pasadena, CA; Sergio Fazio, Oregon Health & Science University, Portland, OR.

Gregory A. Nichols, PhD, stated, "The collaborative efforts between Kaiser, Amarin, and Dr. Fazio enabled data analysis to determine the cardiovascular risk profile of a cohort of patients with high triglyceride levels despite statin therapy. This patient risk profile, which may affect millions of patients, has not been previously described in a real-world dataset."

Sergio Fazio, MD, PhD, stated, "These results support long established knowledge that statin-treated patients with persistent high TG levels in combination with other risk factors remain at elevated risk of future cardiovascular events. The REDUCE-IT trial should provide important information about the effects, if any, of prescription EPA as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy and LDL-C at target goal, have triglyceride levels in the range 150-499 mg/dL at baseline."

Potential limitations of this real-world data include the observational, retrospective nature of the study which can add to uncertainty regarding findings as compared to prospectively collected data, the potential for inaccurate recording of health events in the database and missing data which may limit the usefulness of the findings. A biomarker such as triglycerides may not be causally related to the clinical event as supposed.

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.

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. 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 statements related to scientific presentations from real-world evidence and other studies. These statements are not promises or guarantees related to the potential for favorable outcomes from the ongoing REDUCE-IT cardiovascular outcomes trial. 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 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 Amarin communicates with its investors and the public using the company website (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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