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Real-World Data Supports Association Between Elevated Triglyceride Levels and Increased Cardiovascular Events and Healthcare Costs

BEDMINSTER, N.J. and DUBLIN, Ireland, March 12, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular (CV) health, announced the presentation of a poster today at the American College of Cardiology 67th Annual Scientific Session and Expo in Orlando, Florida. This analysis reinforces that statin-treated patients at high CV risk with controlled LDL-cholesterol (LDL-C) and elevated triglyceride (TG) levels, TG ≥ 150 mg/dL, had worse CV outcomes and higher overall healthcare costs than statin-treated patients with controlled LDL-C and normal TG levels, TG < 150 mg/dL, and normal HDL-cholesterol, HDL-C > 40 mg/dL.

The poster was titled "Triglycerides ≥ 150 mg/dL Associated With Greater Risk of Cardiovascular Events, Costs, and Resource Utilization in High-Risk Statin-Treated Patients With Controlled Low-Density Lipoprotein Cholesterol: A Real-World Analysis." The database utilized for the analysis had millions of de-identified medical records from patient experience within a leading national information and technology-enabled health services business.

Patients with diabetes mellitus and/or established atherosclerotic cardiovascular disease were followed longitudinally for up to five years. Those patients with elevated TG levels, defined as TG ³ 150 mg/dL, as compared with the normal TG group defined as TG < 150 mg/dL and HDL-C > 40 mg/dL, were at increased risk of adverse CV outcomes after multivariable adjustment as follows:

- 26% increased risk for the composite initial major adverse CV event (MACE) (95% confidence interval [CI] 1.19-1.34)
  - The increase in composite MACE in the elevated TG group was driven by a 32% (95% CI 1.20-1.45) increased risk of non-fatal myocardial infarction and a 46% (95% CI 1.33-1.61) increased risk of coronary revascularization
- 12% higher average total healthcare cost (95% CI 1.08-1.16)
- 13% higher rate of occurrence of initial inpatient hospital stay (95% CI 1.10-1.17)

This study, in concert with real-world evidence posters presented previously from two separate studies of patients with different demographics and health care options, support previous findings that patients with elevated TGs have increased risk of future cardiovascular events, even when LDL-C is controlled with statins. This analysis was not based on specific treatment groups; these studies were based on patients with elevated/high and normal TGs while controlling for other factors. Along with genetic and epidemiologic studies, these real-world data further affirm the association of elevated TGs in patients with residual risk that remains after statin control of LDL-C.

The authors of this study were Peter Toth, MD, PhD, CGH Medical Center, Sterling, IL, and Johns Hopkins University School of Medicine, Baltimore, MD; Craig Granowitz, MD, PhD, Amarin Pharma, Inc., Bedminster, NJ; Michael Hull, MS, Djibril Liassou, BA, & Amy Anderson, MS, Optum, Eden Prairie, MN; Sephy Philip, RPh, PharmD, Amarin Pharma, Inc., Bedminster, NJ.

"Research continues to show the association of elevated and high triglycerides with cardiovascular risk and healthcare costs," said Peter Toth, MD, PhD. "Continued research in this area is needed to find safe and effective therapeutic options to combat the growing public health crisis of cardiovascular disease."

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 statements related to scientific presentations from real-world evidence data. 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 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.

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